Investigation Report
of the
Special Demand Committee

Board of Directors of Cardinal Health, Inc.

April 12, 2013

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EXECUTIVE SUMMARY

In Fall 2012, the Board of Directors (the "Board") of Cardinal Health, Inc. ("Cardinal Health" or the "Company") received a letter purporting to be a shareholder demand pursuant to Ohio Rev. Civ. P. 23.1, *et seq.* (the "Demand Letter" or the "Letter"). The Letter asserts that the Immediate Suspension Order that the Drug Enforcement Agency (the "DEA") issued to the Company in February 2012 (the "2012 ISO") was the result of a failure by the Company "to implement systems to detect and prevent the diversion of controlled substances into the illegal market." (Demand Letter at 1.) Further, the Letter alleges that the Directors and Officers of the Company breached their fiduciary duties when they "knowingly and/or recklessly failed to establish" such a system, in violation of the Controlled Substances Act and the Memorandum of Agreement between the Company and the DEA in 2008 (the "2008 MOA"). (*Id.* at 10.)

On November 2, 2012, the Board appointed a special demand committee (the "Special Committee" or the "Committee") to investigate and evaluate the Demand Letter. The Special Committee is composed of the two most recent additions to the Board, Clayton M. Jones, who has been a Director since September 2012 and is not named in the Demand Letter, and Dave P. King, who has been a Director since September 2011. The Special Committee retained Milbank, Tweed, Hadley & McCloy LLP ("Milbank") to assist with the investigation. Milbank collected and reviewed over 15,000 pages of relevant material dating from as early as 2005 to as late as 2012. Milbank also conducted interviews of twenty Company employees, two Audit Committee members, and counsel for the shareholder. Thirteen of the interviews were conducted in person and ten were conducted by telephone, and the length of the interviews ranged from approximately one to three hours. The Special Committee concludes that the document review and interview process was methodical and comprehensive.

Based on the information the Committee gathered during its investigation, and its understanding of the applicable law, the Committee does not believe that it is in the best interest of the Company to pursue claims for breach of fiduciary duty against the Directors and Officers of the Company, as requested by the Demand Letter. The investigation shows that the Board at all times acted diligently and in good faith to fulfill its duties to the Company and the Company's shareholders.

A director will be liable for damages only "if it is proved by clear and convincing evidence . . . that the director's action or failure to act involved an act or omission undertaken with deliberate intent to cause injury to the corporation or undertaken with reckless disregard for the best interests of the corporation." Ohio Rev. Code § 1701.59(E). Directors satisfy their obligation to remain informed of the corporation's activities if a reasonable information and reporting system exists within the company. *See In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 970-71 (Del. Ch. 1996). Where a reporting system exists, "[d]irectors will be potentially liable for breach of their oversight duty only if they ignore 'red flags' that actually come to their attention, warning of compliance problems." *Stanley v. Arnold*, No. 1:12-CV-482, 2012 WL 5269147, at *6 (S.D. Ohio Oct. 23, 2012) (quoting *Forsythe v. CIBC Emp. Private Equity Fund*, No. 657-N, 2006 Del. Ch. LEXIS 60, at *7 (Del. Ch. Mar. 22, 2006)).

Following the 2008 MOA, the Company implemented an extensive and robust system of internal controls to detect and report suspicious orders of controlled substances. The Company

hired new management with extensive regulatory and/or pharmaceutical experience, including a Chief Compliance Officer, a Senior Vice President of Quality and Regulatory Affairs, and a Vice President of Anti-Diversion, and built an anti-diversion group with experienced investigators, pharmacists, and analysts to review potential new customers and to monitor existing customers for risks of diversion. Further, the Company assigned "threshold" ordering volumes for each customer based on a statistical analysis of ordering data, and created an electronic monitoring system to track customers' orders against their pre-assigned threshold limits. The Company continued to enhance the electronic monitoring system and the underlying data. In addition, the Company developed a model to evaluate existing customers against customers that had been terminated as posing unreasonable risks of diversion, and hired a University Professor to test the model. A centralized database was created to store and track data on customers and orders, thereby facilitating the monitoring and investigation process. The Company created extensive policies and procedures applying to anti-diversion personnel, as well as the sales force and personnel in the distribution centers, including procedures for vetting new customers and monitoring orders from existing customers. The Company administered general anti-diversion training to thousands of employees, as well as targeted training on the specific policies and procedures that applied to each job function. The Board was fully informed of the implementation of these anti-diversion measures, and received regular and detailed progress reports throughout the process.

There were no red flags that the Company's new anti-diversion controls were inadequate. The general reaction to the 2012 ISO was surprise, for a number of reasons. Management and key anti-diversion personnel were of the impression that the anti-diversion system was meeting or exceeding the Company's obligations to detect and report suspicious orders. The Company benchmarked the system against those of its competitors to the extent that it could, and hired outside consultants to test and improve upon the system. The Company received little, if any feedback from the DEA about the new system. As part of the 2008 MOA, the DEA visited the Company's corporate headquarters in Dublin to review the new anti-diversion measures and inspected five distribution centers. Although the DEA identified some issues with one of these facilities, the Company rectified those issues and the DEA did not take any formal action. Moreover, the DEA conducted numerous routine inspections of these and other distribution centers from 2008 through the end of 2011, issued no negative findings regarding the anti-diversion controls in place at any of the facilities, and, during some of the inspections, made positive comments indicating that they were impressed, or at least satisfied with the compliance measures that were in place at the facilities. Management informed the Board of the successful inspections. Management also informed the Board of the results of the electronic monitoring system, in particular, the fact that it flagged thousands of orders and led the Company to terminate and report many customers, and reduce the volume of controlled substances being distributed to many other customers. The Board was also informed that enhancements to the system in 2011 increased the accuracy of the system and significantly reduced the number of "false positives," or legitimate customers whose orders were flagged.

The Demand Letter fails to identify a single red flag following the 2008 MOA that would have indicated that the Company's anti-diversion measures were inadequate. Instead, the Letter tries to draw a connection between the allegations that the DEA levied against the Company in the suspension orders and order to show cause it issued in 2007 and 2008 (the "2007/2008 Action") and the allegations at issue in 2012. In other words, the events surrounding the

2007/2008 Action were the red flags that the anti-diversion measures were inadequate leading up to the 2012 ISO. The problem with this theory is two-fold. First, as discussed, the Company instituted an entirely new anti-diversion system following the 2007/2008 Action. The Lakeland, Florida distribution center that was suspended by the 2012 ISO, one of the facilities at issue in the 2007/2008 Action, had been reinstated in late 2008, and underwent a successful inspection by the DEA pursuant to the 2008 MOA in early 2009 and a successful cyclical inspection by the DEA in 2010. Second, the events at issue in the 2012 ISO were different from those at issue in the 2007/2008 Action. The 2012 ISO involved the sale of oxycodone, while the 2007/2008 Action involved the sale of hydrocodone. In addition, the pharmacies at issue in the 2012 ISO were different from those at issue in 2007/2008 Action. Lastly, the 2012 ISO apparently stemmed from an unannounced shift by the DEA to a strict emphasis on volume, both for retail independent pharmacies, as well as for chain pharmacies.

Moreover, the facts surrounding the pharmacies at issue in the 2012 ISO make clear that the Company's anti-diversion system did not fail, but largely succeeded. Indeed, the electronic monitoring system alerted personnel to the increased orders from each of the four pharmacies at issue in the 2012 ISO, and at least one investigator alerted his superiors to certain indicators of diversion at the independent pharmacies. Certain individuals decided not to terminate those pharmacies for a time. Ultimately, the Company terminated the two independent pharmacies as customers, and significantly decreased its shipments of oxycodone to the two chain pharmacy stores at issue, months before the 2012 ISO.

The factual and legal deficiencies in the proposed action make it reasonably likely that the action would be dismissed before a decision on the merits, or that the action would conclude with a finding that the directors and officers fulfilled their fiduciary duties to the Company. The facts make clear that the Company implemented a robust system of internal controls to detect and report suspicious orders, and that the Board was well-informed of those controls. The directors did not fail to act in the face of any red flags that the Company's anti-diversion controls were inadequate.

The Committee also concludes that a review of other factors supports its determination that litigation of the sort requested in the Demand Letter is not in the best interests of the Company. The Committee employed its business judgment to consider all of the corporate interests that may weigh in favor of pursuing the proposed action. The proposed action would be certain to consume tremendous Company resources, and would present a significant distraction for management and employees of the Company. In addition, it is likely that the Company would be obligated to indemnify the directors for their costs in defending against the proposed action, pursuant to the Indemnification Agreement that nearly all of the present and former directors signed, or the indemnification provision contained in the Restated Code of Regulations of Cardinal Health, Inc., which applies to the remainder of the directors. The Committee finds that the expense of reimbursing the directors for litigation costs weighs against accepting the demand to pursue claims with a limited probability of success.

For the foregoing reasons, the Special Committee recommends that the Company not pursue the action requested by the Demand Letter.

REPORT OF THE SPECIAL DEMAND COMMITTEE

I. THE DEMAND

A. Allegations

On September 28, 2012, Faruqi & Faruqi, LLP sent a letter purporting to be a "Shareholder Demand Pursuant to Ohio R. Civ. P. 23.1, *et seq.*" (the "Demand Letter" or the "Letter") on behalf of Isabelle Rauch, a purported shareholder of Cardinal Health, Inc. ("Cardinal Health" or the "Company"), to George S. Barrett, Chairman of the Board of Directors (the "Board") of the Company. The Letter alleges that the Order to Show Cause and Immediate Suspension of Registration issued by the Drug Enforcement Agency (the "DEA") in February 2012 regarding the Company's Lakeland, Florida distribution center (the "2012 ISO") was the result of a failure by the Company "to implement systems to detect and prevent the diversion of controlled substances into the illegal market" in accordance with the Controlled Substances Act (the "CSA"), the Memorandum of Agreement entered with the DEA in 2008 (the "2008 MOA"), and DEA "directives."[1] (Demand Letter at 1, 10.) Further, the Letter alleges that certain "Directors and Officers," defined as twenty-two present and former directors, "breached their duties of loyalty and care when they knowingly and/or recklessly failed to establish" such a system of internal controls. (*Id.* at 10.)

About four pages of the ten-page letter describe the three Orders to Show Cause and Immediate Suspensions of Registration issued against the Company in 2007 (the "2007 ISOs"), the Order to Show Cause issued in 2008 (together with the 2007 ISOs, the "2007/2008 Action"), the Memorandum of Agreement entered into with the DEA in 2008 (the "2008 MOA"), and the civil penalty levied in connection with the 2008 MOA. (*Id.* at 2-5.) The Letter details the DEA's allegations in the 2007/2008 Action that the Company distributed excessive quantities of hydrocodone and failed to maintain effective controls against diversion at seven of its twenty-seven distribution centers. (*Id.*) As further described in the Letter, the Company agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." (*Id.* at 4.) The Letter then discusses the 2012 ISO issued in connection with the Lakeland, Florida facility, one of the facilities that was suspended in 2007, and the DEA's allegation that the Lakeland facility distributed excessive volumes of oxycodone to four Florida pharmacies despite "warning signs," and thus did not have adequate controls in place. (*Id.* at 5-8.) According to the Letter, "[i]t was widely reported that the Company's failure to comply with the 2008 MOA was at least a partial basis for the 2012 ISO." (*Id.* at 7 (citing Declaration of Michele M. Leonhart, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 24, 2012) ("Leonhart Decl."), ¶ 18 ("Although the drugs

[1] As will be discussed, the CSA requires Cardinal Health, as a distributor of controlled substances, to operate a system to detect suspicious orders of controlled substances, and further requires the Company to report such orders to the DEA. (*See infra* Part IV.B.3.c.) As part of the 2008 MOA, the Company agreed, among other things, to implement a system in which "[o]rders that exceed established thresholds and criteria will be reviewed by a Cardinal employee trained to detect suspicious orders for the purpose of determining whether (i) such orders should not be filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels." (2008 MOA at 3.)

and the end customers were different, the common thread was Cardinal Lakeland's inadequate anti-diversion measures. The results of the recent investigation strongly indicated to me that, contrary to its promises in the 2008 MOA, Cardinal had not maintained adequate anti-diversion measures at its Lakeland facility.")).)

The Letter claims that, as a result of the 2012 ISO, the Company "has and will continue to suffer significant harm and incur substantial costs, including, but not limited to, potential fines, attorneys' fees, consulting fees, loss of business, and reputational harm," as well as damage to the Company's "corporate image and good-will." (Demand Letter at 9.) Finally, the Letter demands that the Board "take action against the Directors and Officers to recover the damages described herein for the benefit of the Company." (*Id.* at 10.)

B. Formation of Special Demand Committee

On November 2, 2012, the Board appointed a special demand committee (the "Special Committee" or the "Committee") to investigate and evaluate the Demand Letter. The Special Committee is comprised of the two most recent additions to the Board, Clayton M. Jones, Director since September 2012, and Dave P. King, Director since September 2011. Mr. Jones, who is not named in the Demand Letter, is Chairman and Chief Executive Officer of Rockwell Collins, Inc., an aviation electronics and communications equipment company, and is a Director of Deere & Company, an agricultural and construction machinery manufacturer. Mr. King is President, Chief Executive Officer, and Chairman of Laboratory Corporation of America Holdings, an independent clinical laboratory company. After receiving proposals from four law firms, and interviewing two firms, the Special Committee retained Milbank, Tweed, Hadley & McCloy LLP ("Milbank") to assist with the investigation.

II. RELEVANT LEGAL STANDARDS

Ohio law provides that "[a] director shall be liable in damages . . . only if it is proved by clear and convincing evidence . . . that the director's action or failure to act involved an act or omission undertaken with deliberate intent to cause injury to the corporation or undertaken with reckless disregard for the best interests of the corporation." Ohio Rev. Code § 1701.59(E). Directors satisfy their obligation to remain informed of the corporation's activities if an information and reporting system exists within the company that will provide senior management and the directors with accurate and timely information "sufficient to allow . . . informed judgments concerning . . . the corporation's compliance with [the] law . . . ." *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959, 970-71 (Del. Ch. 1996).[2] Where a reporting system exists, "[d]irectors will be potentially liable for breach of their oversight duty only if they ignore 'red flags' that actually come to their attention, warning of compliance problems." *Stanley*, 2012 WL 5269147, at *6 (quoting *Forsythe v. CIBC Emp. Private Equity Fund*, No. 657-N, 2006 Del. Ch. LEXIS 60, at *7 (Del. Ch. Mar. 22, 2006)). Accordingly, "with an effective compliance system

[2] "The law does not presume that the directors of a large organization like Cardinal Health are aware of every action by every employee or every sale to every customer." *Stanley v. Arnold*, No. 1:12-CV-482, 2012 WL 5269147, at *6 (S.D. Ohio Oct. 23, 2012) (citing *Caremark*, 698 A.2d at 971 ("[O]f course, the duty to act in good faith to be informed cannot be thought to require directors to possess detailed information about all aspects of the operation of the enterprise . . . .")).

in place, corporate directors are entitled to believe that, unless red flags surface, corporate officers and employees are exercising their delegated corporate powers in the best interest of the corporation."[3] *Forsythe v. ESC Fund Mgmt. Co. (U.S.)*, No. Civ. A. 1091-VCL, 2007 WL 2982247, at *7 (Del. Ch. Oct . 9, 2007).

III. THE INVESTIGATION

A. Document Collection and Review

Milbank worked closely with the Company to collect documents relevant to the allegations contained in the Demand Letter, including documents relating to the Company's anti-diversion policies and procedures, as well as communications and materials provided to the Board and the Audit Committee about those policies and procedures. The Company cooperated with the investigation fully and at all times. In total, Milbank collected and reviewed over 15,000 pages of relevant material dating from as early as 2005 to as late as 2012. These documents included Standard Operating Procedures ("SOPs") and handbooks relating to anti-diversion measures, internal Company training materials, corporate governance guidelines and charters, and organizational charts. Milbank also reviewed the extensive court filings and accompanying exhibits from the 2012 proceedings with the DEA before the Administrative Law Judge, the District Court for the District of Columbia, and the United States Court of Appeals for the District of Columbia, as well as court filings and exhibits from the three derivative actions filed against the Board in May and June 2012. In addition, Milbank reviewed all Board and Audit Committee minutes from late 2007 to early 2012, as well as materials and communications conveyed to the Board and the Audit Committee during that time and relating to anti-diversion and other DEA-related issues, such as slide decks, reports, memoranda, and emails.

A team of Milbank attorneys reviewed each document to determine its significance to the investigation. The Special Committee concludes that Milbank's document collection and review was thorough and systematic.

B. Interviews

Milbank conducted interviews of twenty Company employees and two Audit Committee members. Milbank worked closely with the Company to identify the types of employees who would be most directly involved with anti-diversion measures, and to compile a representative group of such employees. Specifically, Milbank interviewed the following Company personnel: one salesperson (Thomas Convery); one analyst in Quality and Regulatory Affairs ("QRA") (Shirlene Justus); two pharmacists in QRA (Christopher Forst and Doug Emma); two compliance officers in QRA (Joyce Butler and Kay Gagliardi); two investigators in QRA (Vincent

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[3] "[C]ourts routinely reject the conclusion that because illegal behavior occurred, internal controls must have been deficient, and the board must have known so." *Stanley*, 2012 WL 5269147, at *6 (citing *Desimone v. Barrows*, 924 A.2d 908, 940 (Del. Ch. 2007)); *see also In re Lear Corp. S'holder Litig.*, 967 A.2d 640, 653 (Del. Ch. 2008) ("[E]ven the most diligent board cannot guarantee that an entire organization will always comply with the law"); *Stone v. Ritter*, 911 A.2d 362, 373 (Del. 2006) ("[T]he directors' good faith exercise of oversight responsibility may not invariably prevent employees from…causing the corporation to incur significant financial liability . . . .").

Moellering and Harvey Florian); both the current and former director of investigations (Ullrich Mayeski, a former regional director overseeing compliance officers, and Steve Morse, respectively); two senior vice presidents in the pharmaceutical distribution group (Steve Lawrence, for retail independent pharmacies, and Jim Scott, for national chain pharmacies); a Director of Operations Management for a distribution center (Scott McBride); Associate Chief Regulatory Counsel (Gary Cacciatore); Associate General Counsel (Michael Moné, the former Vice President of Anti-Diversion); the Chief Legal and Compliance Officer (Craig Morford); the Senior Vice President of QRA (Gilberto Quintero); the Vice President of QRA, Supply Chain Integrity (Todd Cameron); the Vice President of QRA, Pharmaceutical Distribution (Steve Reardon); and the Director of Operations and SOM Compliance (Nicholas Rausch). Corey Goldsand, in-house Counsel for the Company, was present as a facilitator for each of the interviews, but did not ask questions. Milbank also interviewed John Finn and Glenn Britt, of the Audit Committee, in the presence of Steve Falk, General Counsel, and counsel from Jones Day. Lastly, Milbank interviewed counsel for the shareholder, Lindsay Roseler and Michael Hynes, of Faruqi & Faruqi, LLP. Thirteen of the interviews were conducted in person, and ten of the interviews were conducted by telephone. The length of the interviews ranged from approximately thirty minutes to three hours, with most interviews lasting about one to two hours.

The purpose of interviewing upper-level management was to understand the Company's anti-diversion measures as they apply to those individuals and the individuals in their departments, how those measures changed since 2007 and the reasons for those changes, and how those changes were communicated to the Board. For lower-level employees, the goal of the interviews was to determine their knowledge of the anti-diversion policies and procedures as they apply to their job functions, how those policies and procedures evolved from 2007 through 2012, whether employees adhere to those policies and procedures in the day-to-day execution of their duties, and the effectiveness of training programs relating to anti-diversion. The purpose in interviewing the Audit Committee members was to verify that the Board and the Audit Committee were informed about the Company's anti-diversion measures, as well as any diversion problems or issues.

The Special Committee concludes that Milbank's interviews were comprehensive, both in terms of the topics addressed and the individuals who were interviewed.

IV. ANTI-DIVERSION POLICIES AND PROCEDURES

A. Anti-Diversion Measures Before the 2007 ISOs

In the years preceding the 2007 ISOs, the Company's anti-diversion measures focused mainly on preventing price diversion[4] and diversion by internet pharmacies. There was a small group of employees involved in anti-diversion measures, including a Vice President of QRA, a QRA director, and employees at each division who were responsible for some compliance-related tasks, in addition to non-compliance responsibilities.

[4] "Price diversion" refers to the practice of non-retail pharmacies purchasing pharmaceuticals from a wholesaler at contract or discount prices, and then reselling the pharmaceuticals at higher prices on the open market.

During this time, there was no electronic system for analyzing orders. The Company relied on sales data from the previous month, and thus there was a thirty-day lag time for information. In addition, most of the files on customers and orders were on paper, rather than electronic, and located in various places. In August 2005, Cardinal Health met with the DEA to discuss internet pharmacies and the DEA provided the Company with monthly dosage unit quantities for hydrocodone, phentermine, and alprazolam to assist with monitoring for internet pharmacy activity. The Company implemented a system to review customer orders based on that data, and also provided the information to sales personnel. Further, each division provided a monthly Ingredient Limit Report to the DEA, which identified customers whose monthly purchase quantities exceeded certain predetermined amounts. (Required Reports to DEA, June 15, 2006, at 6.) In addition, employees in the distribution centers were expected to identify and report suspicious or excessive purchases of controlled substances to their superiors.

The evaluation of new customers during this time focused on whether the pharmacy allowed customers to order prescriptions over the internet or filled prescriptions for customers of other internet pharmacies. (Internet Pharmacies: Customer Approval and Oversight Policy, Apr. 13, 2007, at 1.)

During Spring and Summer 2006, there were live training sessions for employees at six locations around the country, focused primarily on price diversion and diversion by internet pharmacies. The Company also developed and implemented two mandatory computer-based trainings in August and December 2007 for all sales personnel and field operations managers, which also focused on internet pharmacy diversion.

B. Anti-Diversion Measures from the 2007 ISOs through the 2012 ISO

Before 2007, the DEA's enforcement efforts seemed to be primarily aimed at internet pharmacies. The 2007/2008 Action signaled to the Company that the DEA's enforcement efforts had expanded to include distributors, particularly with respect to sales to retail independent pharmacies affiliated with internet pharmacies. In response to the 2007/2008 Action, and in an attempt to try to anticipate the DEA's next area of focus, the Company set out to build a new anti-diversion program. Over time, the Company added more than forty positions and invested approximately $25 million in the new system. (Declaration of Craig Morford Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA Administrative Law Judge ("ALJ") Apr. 12, 2012) ("Morford Decl."), ¶¶ 5, 7.)

In December 2007, the Company hired Michael Moné as Vice President of Anti-Diversion, within QRA. (Amended Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 6, 2012) ("Feb. 6 Moné Decl."), ¶ 3.) Moné was a pharmacist and an attorney, whose prior experience included representing the Board of Pharmacy as counsel with the Florida Department of Professional Regulation, representing the Boards of Chiropractic, Osteopathic Medicine, and Veterinary Medicine as Assistant Attorney General in Florida, and acting as Executive Director of the Kentucky Board of Pharmacy. (*See id.* ¶ 2.) One of Moné's first actions was to build out the anti-diversion group. In February and March 2008, Moné hired Steve Morse and Christopher Forst, both pharmacists, as Directors of Supply Chain Integrity. Morse hired four investigators, whom he would oversee in conducting investigations and site visits of customers. Forst would handle the

pharmaceutical analysis of customers, and would later hire two additional pharmacists to assist with that review. Nicholas Rausch, a consultant with the Company who assisted with the early investigations of customers, was brought in to the anti-diversion group in 2007 as a Manager of Supply Chain Integrity. Rausch, who was later promoted to Director, would oversee the New Account Specialists, or "analysts," and would be responsible for the development and implementation of an electronic monitoring system. In addition, the Company hired twenty-four compliance officers, who would be based at the Company's distribution centers and would oversee various compliance measures, including the anti-diversion measures applying to distribution centers. The compliance officers would be part of the QRA group and would report to Steve Reardon, Vice President of QRA, via regional directors.

In May 2008, the Board brought in a new Chief Compliance Officer, Craig Morford, with a mandate to establish a premier anti-diversion system. Morford had extensive leadership and regulatory experience, as a former U.S. Attorney for the Middle District of Tennessee and the Eastern District of Michigan and the former Acting U.S. Deputy Attorney General, overseeing the various U.S. Attorney offices and agencies within the Justice Department. (Morford Decl. ¶ 2.) In 2009, the Company hired Gilberto Quintero as the new Senior Vice President of QRA, reporting directly to Morford. (Declaration of Gilberto Quintero Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 13, 2012) ("Quintero Decl.") ¶ 4.) Quintero came to the Company with extensive experience in regulatory and compliance issues from his former role at Wyeth Pharmaceuticals. (*Id.* ¶ 3.)

The Company set a strong tone that anti-diversion was the responsibility of every employee. (Morford Decl. ¶ 5.) By the end of 2008, the Company had begun implementing a host of new policies and procedures designed to detect and report suspicious orders. In particular, the Company implemented detailed procedures for reviewing potential new customers and for monitoring existing customers. The procedures for reviewing potential new customers would apply to the anti-diversion group, as well as the salespeople in the field. (Suspicious Order Monitoring Presentation, Feb. 2009, at 7-10.) The monitoring of existing customers would involve the creation of a new electronic monitoring system (at times referred to as the "Suspicious Order Monitoring" or "SOM" system), as well as specific duties for the anti-diversion group, the salespeople, and the employees at the distribution centers. (*Id.* at 7-14.) The Company administered extensive mandatory training on the anti-diversion policies and procedures. (*Id.* at 15-16.) The Company hired consultants to review and test the anti-diversion system, and tried to gauge the DEA's response to the system in communications with DEA personnel and by carefully observing the DEA's cyclical inspections of distribution centers.[5]

1. Review of Potential New Customers

In January 2008, the Company issued standard operating procedures ("SOPs") that required the anti-diversion group to evaluate any potential new retail independent customer to

[5] The DEA conducts routine cyclical inspections (sometimes referred to as "audits") of manufacturers and distributors of controlled substances and regulated chemicals.

determine whether it posed a risk of diversion.[6] (New Retail Independent Customer Survey Process ("New Customer Survey Process"), Jan. 4, 2008, at 1-2; New Account Approval, Dec. 22, 2008, at 1; *see also* Suspicious Order Monitoring Presentation, Feb. 2009, at 10; Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011, at 5.) The procedures required salespeople, in conjunction with the potential new customer, to complete a New Retail Independent Pharmacy Questionnaire, commonly referred to as a "Know Your Customer"[7] questionnaire (the "New Customer Questionnaire"). (New Customer Survey Process, at 1.) The New Customer Questionnaire required information about the pharmacy's business, including the pharmacy's DEA and state licenses, whether there were any prior disciplinary actions, such as revocation or suspension of licenses, the method by which the pharmacy received prescriptions, whether the pharmacy filled prescriptions for out of state patients, the pharmacy's expected usage for certain products, and whether there were any local pain or weight loss clinics in the area and the proximity of any such clinics. (*See* New Customer Questionnaire, Jan. 4, 2008.) The procedures also required the salespeople to take photos of the interior and exterior of the pharmacy and to send the photos to the anti-diversion group for review. In addition, all new retail independent customers were required to sign a DEA compliance agreement titled, "Compliance Representations and Warranties for Pharmacy Customers." (New Customer Survey Process, at 2.)

The anti-diversion group was responsible for the review and analysis of potential new accounts. (New Account Approval, Dec. 22, 2008, at 1.) In 2010, three analysts were hired to focus on reviewing potential new accounts. The analysts reviewed the New Customer Questionnaires to verify the information that the customer provided and look for common indicia of diversion, such as high percentage of cash payments, unjustifiably high percentage of controlled substance sales, and out-of-state patients or prescribers. (*See* New Customer Survey Process, at 2; Declaration of Nicholas Rausch Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 13, 2012), ¶ 11.) If there were any concerns, a pharmacist in the anti-diversion group would review the data on the potential new customer and decide whether to open the account, refer the case for additional investigation, or decline the account. (Feb. 6 Moné Decl. ¶ 12.)

For new chain pharmacy customers, the Company would obtain information about the chain's number of stores, anticipated usage, and internal anti-diversion procedures. (Feb. 6 Moné Decl. ¶ 13.) If a chain sought to open a new pharmacy, the corporate office would need to provide Cardinal Health with the new pharmacy's state license and DEA registration. (*Id.* ¶ 14.)

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[6] Regarding the SOPs generally, the actual practices were constantly being improved or modified, and those changes would be reflected in subsequent versions of the SOPs. With respect to the New Customer Survey Process, a revised version was issued in October 2009.

[7] "Know Your Customer" or "KYC" is a term used within the Company to refer to the diligence measures for reviewing and monitoring potential and existing customers.

2. Monitoring Existing Customers

a. Electronic Sales Monitoring

In 2007, the Company began building out the technology and infrastructure for an electronic system that would store data about customers and monitor orders. At that time, the Company's data on customers was located in various places and largely on paper. Further, there was no analytical capability or real-time data for reviewing orders. Moné and Rausch worked with the Company's IT group to build the electronic monitoring system. The system was built on top of the order fulfillment system, so that it could draw from the data in the order fulfillment system.

In late 2007 through early 2008, the Company implemented the basic components of the electronic monitoring system. The Company engaged Deloitte to help develop the analytical methodology for setting thresholds. In 2008, Moné and Rausch began conducting informal "benchmarking" of the electronic monitoring system, engaging in arms' length communications with other distributors about their respective systems. Those efforts continued through the years.

In 2010, the Company partnered with IBM to create Anti-Diversion Centralization ("ADC"), a central repository that allowed all data on a particular customer to be stored and accessible on a single platform. (Quintero Decl. ¶ 7.) The new system made the process of reviewing customers much easier, both for pharmacists reviewing orders and for investigators preparing for site visits, because all of the data on customers was captured in one place. In addition, ADC provided a better sense of the "whole picture," showing more comprehensive and detailed information about the customer. The program showed all of the information that had been collected about the customer, prior held orders, communications about prior held orders, and graphs depicting previous orders and fluctuations in orders, all of which assisted pharmacists in reviewing orders. ADC also captured the pharmacists' decisions about whether to release the order and allow it to be filled or to delete the order and not allow it to be filled.

(i) Setting Thresholds

When the electronic system was created in 2008, thresholds were set by identifying a "baseline" drug quantity for one month, using the mean volume for each drug family for each class of trade. The customers were segmented into four main classes of trade: retail independents, chains, hospitals, and long-term care.[8] The stores were segmented by size (small, medium, and large) and thresholds were set for each size category using multiples of 3, 5, or 8, depending on the drug family, based in part on multiples that the DEA had previously provided

[8] The system first focused on the four highest risk drugs and on retail independent pharmacies, because those were the pharmacies at issue in the 2007/2008 Action and were thought to pose the highest risk of diversion. As 2008 progressed, the remaining 106 drugs were included and the system was expanded to include long-term care, then hospitals, and then chain pharmacies.

for certain combination products[9] containing those controlled substances. Thus, the system was designed to create an "alert" if the volume for a particular store exceeded the assigned threshold.

If a new retail independent pharmacy provided ordering and dispensing information, a pharmacist would create a customized threshold for the pharmacy, taking into account the size and location of the pharmacy, its history of dispensing, the normal wholesale package size of drugs ordered, the number of different strengths within a given family of controlled substances, the availability of generic drugs for the controlled substances, and whether the pharmacy used automated dispensing. (Feb. 6 Moné Decl. ¶ 16.) SOPs issued in December 2008 outlined the specific steps for calculating thresholds: (1) extract and formulate a list of customers that have purchased monitored items and historical sales data for those customers for all monitored items; (2) differentiate customers through segmentation by size and/or specialty; (3) evaluate historical controlled substance sales data per drug family, per month for each customer segment to establish appropriate threshold limits, using the multiples of 3, 5, or 8; (4) incorporate background information about the pharmacies to establish final threshold limits; and (5) apply rounding logic and finalize threshold limits.[10] (Process to Establish SOM Threshold Limits, Dec. 22, 2008, at 2-4.) Thus, a baseline was first established for all "monitored items," which included any controlled substances. (*Id.* at 1.) The baseline was then adjusted up by a statistically significant factor or variable to formulate the threshold limit for the pharmacy. (*Id.*) If a new retail independent pharmacy did not provide dispensing data, the pharmacy would receive the mid-level threshold limit. (Feb. 6 Moné Decl. ¶ 16.) The Company did not inform customers of their threshold limits. (*Id.*)

Thresholds for new chain stores were based on a standard threshold for the entire chain, because chain stores usually have a known ordering pattern for the majority of stores. (*Id.* ¶ 17.) The Company also took into account the chain's anti-diversion measures in setting thresholds. (*See* Supplemental Declaration of Nicholas Rausch Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 23, 2012) ("Rausch Supplemental Decl."), ¶ 5.)

(ii) Monitoring Thresholds

In the beginning, the system was primarily focused on volume, and whether the order was more than two standard deviations away from the mean. As it evolved, it looked at other metrics, many of which were based on guidance that the DEA provided in letters to distributors and manufacturers, such as the ratio of controlled to non-controlled substances and percentage of cash sales. As the system progressed further, it incorporated regression analyses to review volatility, and the behavior of the individual customer. Thus, the flagging of an order for volume triggered a review of other data, such as order frequency and history.

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[9] The DEA provided guidance to chemical distributors approving the use of multiples of three and eight for drug products consisting of a listed chemical and a controlled substance. (*See* Drug Enforcement Administration Office of Diversion Control, "Knowing Your Customer/Suspicious Order Reporting," http://www.deadiversion.usdoj.gov/chem_prog/susp.htm.)

[10] Each of these steps included a number of sub-steps. A revised version of the Process to Establish SOM Threshold Limits was issued in January 2010.

In 2010, Quintero asked the Pricing Analytics group to develop a system to identify outlying customers. In 2011, the Company hired a full time statistician for the purpose of maintaining and enhancing the system. This individual was asked to analyze customers that had been terminated as posing unreasonable risks of diversion to determine if there were similarities in the buying patterns of these customers, both in terms of changes in volumes and combinations of drugs. In June 2011, the Company implemented a logistical regression model that compared those customers to existing customers. Thus, the system would flag independent pharmacies whose ordering patterns began to emulate the ordering patterns of customers previously terminated as posing risks of diversion, prompting additional investigation of the customer.[11] (Feb. 6 Moné Decl. ¶ 22.) The model was validated by the Chair of the Department of Integrated Systems Engineering of Ohio State University. (*Id.*)

The analysts in Rausch's group were responsible for monitoring threshold events. SOPs issued in December 2008 outlined the procedures for the daily reporting of threshold events within the Company.[12] (Daily Threshold Reporting, Dec. 22, 2008, at 1.) In addition, the electronic monitoring system would generate an early dialogue notice when a customer's order caused it to reach 75% of its monthly threshold. (Feb. 6 Moné Decl. ¶ 18.)

b. Monitoring by Salespeople

Salespeople were not usually aware of their customer's thresholds, but they were expected to monitor their customers using other methods. In 2008, the sales force started receiving "Highlight Reports," which were monthly reports that identified "Red Flag" or "Yellow Flag Customers" based on certain percentage increases in their controlled substance orders. (*See generally*, Sales – Highlight Report, Dec. 22, 2008.) SOPs issued in December 2008 required salespeople to visit their Red Flag Customers within ten working days to look for signs of diversion and complete an online Customer Visit form.[13] (*Id.* at 3.) For Yellow Flag Customers, salespeople were required to contact the customer as soon as possible to understand the reason for the increased ordering and look for signs of diversion. (*Id.*) If the customer had been a Yellow Flag Customer for consecutive months, the salesperson or an investigator was required to visit the customer within fifteen business days. (*Id.*) In 2009, the SOPs were revised to define "Red Flag Customers" as customers whose orders of controlled substances or List 1 chemicals increased by 15% (where the increase was at least $10,000), and "Yellow Flag Customers" as customers whose orders increased by 10% (where the increase was at least

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[11] In or around June 2011, the Company also developed multiple linear regression models for chain pharmacies, based on the chains' buying patterns for certain classes of drugs.

[12] The SOPS provided that the IT department would send a report of the order to the anti-diversion group, which would record the order into a master file, create a customer profile to use during the review of the order, and create a "held order report." (Daily Threshold Reporting, Dec. 22, 2008, at 2-3.) The sales group would also be informed of the threshold event. (*Id.* at 4-5.) A revised version of the Daily Threshold Reporting SOP was issued in January 2010.

[13] The Customer Visit form included the following questions, among others: whether there were people loitering or lined up at the pharmacy or local practitioner's office; whether the pharmacy had front-end or over-the-counter merchandise; whether there was a pain management or weight loss clinic located in the general vicinity of the pharmacy; and any other observations by the salesperson. (*See* Supply Chain Services Documentation of Customer Visit form.)

$5,000).[14] (Sales – Highlight Report, June 9, 2009, at 3.) The Highlight Reports were discontinued in or around late 2010, and eventually replaced by ordering data made available to salespeople directly through a program called "Winwatcher." *See infra* Part VI.B.2.b.

Other SOPs issued in December 2008 required salespeople to perform an "early dialogue" with customers whose orders neared their threshold by a certain percentage. (Sales – Early Dialogue, Dec. 22, 2008, at 2.) The procedures required salespeople to contact the customer regarding its increase in ordering to determine whether there was a trend or data that explained the orders, such as seasonality, new business contracts, change in business model, purchase of files, or relocations. (*Id.*) The salesperson was required to document the relevant facts and complete a Customer Visit form. (*Id.* at 2-3.)

Salespeople were expected to visit their customers regularly and to look for signs of diversion on each visit. (*See* Suspicious Order Monitoring Presentation, Feb. 2009, at 8; Declaration of Jon Giacomin Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 12, 2012) ("Giacomin Decl."), ¶ 10.) SOPs issued in December 2008 detailed the "process requirements for the continuous monitoring and reporting of customer order activities by [the sales force]," and listed "anti-diversion alert signals" for the sales force to be aware of when visiting customers.[15] (Sales – Anti-Diversion Alert Signals, Dec. 22, 2008, at 1-2.) The alert signals included: pharmacies with minimal or no front end merchandise, little or no walk-in business, or primarily cash customers, or pharmacies soliciting buyers of controlled substances via the internet; orders containing a high percentage of controlled substances relative to non-controlled substances, or excessive quantities of a limited variety of controlled substances; and one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled. (*Id.* at 2.) The SOPs required the salesperson to complete an online Customer Visit form and to assess a risk level for the customer if two or more of the anti-diversion alert signals were present. (*Id.*)

As discussed above, salespeople were notified if one of their customers experienced a threshold event. (*See supra* note 12.) SOPs issued in December 2008 required the customer to complete a Threshold Event Survey.[16] (Sales – Investigation, Dec. 22, 2008, at 2.) Following completion of the survey, the anti-diversion group might determine that a site visit was necessary and alert the salesperson, who might be asked to accompany an investigator on a site visit of the pharmacy. (*Id.* at 3.)

In 2008, the Company revised the compensation policies for salespeople, to encourage salespeople to report customers who may pose risks of diversion. In particular, the Company instituted a policy that if a customer was terminated as a diversion risk, the salesperson's sales goals would be reduced by the portion attributable to that customer. (*See* Giacomin Decl. ¶ 12.)

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[14] The Sales – Highlight Report SOP was revised again in January 2010.

[15] A revised version of these SOPs was issued in June 2009.

[16] A revised version of these SOPs was issued in June 2009.

c. Monitoring at the Distribution Centers

Compliance officers and other employees at the distribution centers were also responsible for monitoring orders. SOPs issued in April 2009 required compliance officers to review monthly reports of the top twenty-five retail independent purchasers of commonly diverted drugs[17] ("Top 25 Reports"), to identify customers of concern, and to participate in "ride alongs" with salespeople to visit customers of concern.[18] (Compliance Officer: Duties and Responsibilities, Apr. 17, 2009, at 1.)

In addition, the supervisor in the cage/vault area, as well as at least one other employee in the cage/vault, were required to review "Large Order Reports," which would identify all orders over a certain quantity (as identified by the anti-diversion group).[19] (Cage/Vault SOM Process, Dec. 2, 2008, at 1.) The Large Order Reports would be reviewed before the orders were packaged to look for any "Orders of Interest," defined as an order that appears to "significantly deviate" from the customer's normal ordering pattern or the normal ordering pattern for the class of customer. (*Id.* at 1, 3.) Employees were instructed that Orders of Interest could exhibit the following traits, among others: quantity that was not normal for the customer or the customer's class; substance that was not normal for the customer; quantity that has shown signs of a steady increase over time; or substance/quantity that did not match the season. (*Id.* at 3.) If any Orders of Interest were identified, the cage/vault supervisor, based on his or her knowledge or experience, could authorize the shipment or hold the order and not allow it to be filled. (*Id.*) If an order was held, the compliance officer and the anti-diversion group would be notified.[20] (*Id.*)

Orders of Interest could also be identified at any time during the processing and fulfillment of the order. The Company instituted a policy in 2008 that enabled any employee at a distribution center to "raise their hand" and hold an order if it looked unusual. (*See* Suspicious Order Monitoring Presentation, Feb. 2009, at 12; Declaration of Joyce R. Butler Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 12, 2012) ("Butler Decl."), ¶ 13.) The employees in the cage and vault filled orders for the same customers on a regular basis, and thus were in a position to recognize when an order was unusual based on the size of the

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[17] The drugs included hydrocodone and oxycodone. Revised versions of these SOPs were issued in 2009 and 2010.

[18] The requirement for compliance officers to participate in a certain number of ride alongs each year was eliminated in 2010, as it was considered not a good use of the Compliance Officers' time. (*See* Compliance Officer: Duties and Responsibilities, Nov. 12, 2010, at 1.) Ride alongs are now used for training new hires.

[19] Revised versions of the Cage/Vault SOM Process were issued on December 9, 2008, January 21, 2010, April 7, 2010, April 22, 2010, and August 3, 2010.

[20] The customer and the appropriate sales representative were also notified if an order was held at the distribution center. The relevant sales and management team would receive an email describing the held order the following morning.

order and the customer's ordering history. The employees were also trained to recognize indicators of diversion.[21] *See infra* Part IV.B.4.b.

Orders of Interest were treated as threshold events and analyzed accordingly. (Cage/Vault SOM Process, Dec. 2, 2008, at 3.)

3. Responding to Threshold Events

a. Review of Threshold Events by Pharmacists

If a customer experienced a threshold event, i.e., when a customer's orders in a given month exceeded its threshold for a particular drug family, the order causing the overage and any subsequent orders would be held pending review. (Daily Threshold Reporting, Dec. 22, 2008, at 1.) A pharmacist would review the files on the customer and the information about the specific order. (*See* Rausch Supplemental Decl. ¶ 6.) The Company made a concerted effort to hire pharmacists with a variety of pharmaceutical backgrounds. Christopher Forst, Director of Pharmacy Assessment, had many years' experience as a hospital pharmacist. Two additional pharmacists were hired in 2010, with mail order and retail experience.

In December 2008, the Company issued detailed procedures for the review of threshold events. (*See generally,* Threshold Event Review, Self Verification; Decision Making and Threshold Outcome Communication, Dec. 22, 2008 (hereinafter, "Threshold Event Review").) Generally, the procedures required review of the customer's profile to determine the customer's business type, the distributor information (whether Cardinal Health was the primary or secondary distributor),[22] the drug family that triggered the threshold event, the customer's total number of threshold events in general and for the specific drug family at issue, the customer's total current monthly accrual and monthly usage for the specific drug family, and the customer's monthly drug family limit. (*Id.* at 1-2.) The procedures then required review of the specific order to determine the type of drug family products in the held order, the quantity of drug family products in the held order, and the reasonableness of the total drug family order. (*Id.* at 6.) Next, the procedures called for certain decisions to be made by an individual with a degree in pharmacy, including: (1) whether the order was reasonable based on applied reasoning (looking at such factors as seasonal events, natural events, regional prescribing habits, the location of the pharmacy or facility in relation to health care providers, whether it was an end of month order, whether there was a shortage of other products, or whether the monthly limit was incorrect); (2) whether the order was excessive (for example, as a result of an order entry error or duplication); and (3) whether the order was suspicious (i.e., excessive in quantity, strength, or frequency, or an unexplainable deviation from the norm). (*Id.*)

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[21] Employees in the cage and vault undergo rigorous screening, training, and certification processes before they are granted access to controlled substances, in accordance with DEA requirements and detailed SOPs in existence since at least May 2008. (*See, e.g.*, Personnel, May 14, 2008; Employee Screening and Training Requirements for DEA Regulated Activities, May 8, 2009, and as revised, Mar. 17, 2010, June 3, 2011, and Feb. 4, 2013.)

[22] Certain chains have their own warehouses and vaults for stocking drugs. For these chains, their primary source is their own warehouse system, and Cardinal Health acts as a secondary distributor, providing "back up" if the chain runs out of, or chooses not to stock, a particular drug.

When an independent retail pharmacy experienced a threshold event, a pharmacist could request that the investigator conduct a "deep dive" investigation of the pharmacy, which included a site visit of the pharmacy.[23] (*See* Threshold Event Review, at 18.) Investigators and pharmacists conducted occasional "surveillance" visits of chain pharmacies, during which they would visit the store without announcing their presence.

Distributors did not typically perform the same diligence on chain pharmacies as they did on retail independent pharmacies. (*See, e.g.*, DEA Pharmaceutical Industry Conference: Wholesale Distribution Diversion Control Program, AmerisourceBergen Corp., Sept. 11, 2007, at 7; Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 13, 2012) ("Apr. 13 Moné Decl."), ¶ 39.) The pharmacies at issue in the 2007/2008 Action were retail independent pharmacies, and chain pharmacies were generally believed to pose lesser risks of diversion than retail independent pharmacies. Pharmacists at chain stores usually do not share in the profits for the store, and chain pharmacies have their own anti-diversion and loss prevention systems.[24] (Feb. 6 Moné Decl. ¶ 10.) Cardinal Health communicated with the chain's corporate offices to supply information regarding orders of concern. (Apr. 13 Moné Decl. ¶ 38.) If a chain pharmacy experienced a threshold event, the Account Manager would contact the chain's corporate office to request information regarding the order at issue and then provide the information to the anti-diversion group for review. The anti-diversion group would review the data on the order and the proffered explanation for the threshold event and respond in one of the following ways: (1) accept the explanation and temporarily increase the threshold to ship the order; (2) accept the explanation and permanently increase the threshold; (3) ask for additional information; or (4) reject the explanation and refuse to ship the order.

If a pharmacist deemed an order reasonable, he or she could release the order and, if warranted, increase the threshold in the electronic system. (Threshold Event Review at 6; *see also* Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011, at 6-7.) A pharmacist could determine that an order was reasonable for a number of reasons. For example, if a customer's business model changed in a way that caused it to grow, an increase in ordering would be expected and the pharmacist might decide that an upward adjustment in the customer's threshold was appropriate. If the pharmacist deemed the order unreasonable and suspicious, he or she would delete the order and not allow it to be filled.[25] (*Id.* at 6-7; *see also* Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011, at 7.) The pharmacist's decision to release the order and allow it to be filled or to delete the order and not allow it to be filled was documented within the electronic system. (Threshold Event Review, at 14.)

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[23] In certain circumstances, pharmacists or analysts might conduct phone interviews of customers rather than conduct site visits.

[24] With respect to CVS in particular, Cardinal Health and CVS conducted a webinar in 2008 in which CVS discussed its loss prevention measures. (Apr. 13 Moné Decl. ¶ 83.)

[25] If the order was unreasonable but was the result of an entry error, the pharmacist would delete the order in the system and not allow it to be filled, but would not report the order. (*Id.*)

b. On-Site Investigations

The vast majority of on-site investigations were conducted in response to threshold events. Investigations would also be conducted at the request of Moné, based on information he received from his contacts in the pharmacy arena. As the electronic system became more advanced, the Company began to conduct proactive investigations in advance of threshold events.

In early 2008, the Company worked with Cedegim, a compliance consulting company, to set guidelines and processes for the investigators to follow. In December 2008, the Company issued detailed SOPs setting out the required procedures for conducting on-site investigations.[26] (On-Site Investigations, Dec. 22, 2008, at 1.) The investigations were comprised of four main components: initial case preparation; background investigation; site visit; and report preparation. (*Id.* at 5-11.) During the initial case preparation stage, the investigator would review the Company's existing files on the customer. (*Id.* at 5.) Based on this information, the investigator would develop a background research plan that included reviewing licensed customer information, threshold events, customer responses to questionnaires, and previous decisions regarding shipment to the customer. (*Id.*)

During the background investigation, the investigator would use various internet resources to verify the information in Cardinal Health's files and conduct the background research on the pharmacy, its employees, local physicians and healthcare facilities, and geographical information. (*Id.* at 6.) The investigator would research any disciplinary actions against the pharmacy or its owners or employees, and any civil or criminal actions taken against the pharmacy, its employees, local physicians, or any other person associated with the pharmacy. (*Id.*) The investigator would then contact an appropriate representative of the pharmacy to schedule and discuss the purpose of the visit. (*Id.* at 7.) The investigator would also contact the salesperson assigned to the licensed customer and offer him or her the opportunity to be present during the site visit. (*Id.*)

Upon entering the community and the vicinity of the pharmacy, the investigators were directed to observe and document the surroundings and to note any specifics relating to business practices, business volume, and business type, such as: the types and number of health care facilities located within the area; the types and number of medical practices, especially noting those who are characteristically heavy prescribers of controlled substances (e.g., pain clinics, orthopedics, surgeons, oncologists, cancer centers, weight loss clinics); unusually large numbers of individuals in the general vicinity of a physician's practice or the pharmacy; and whether the clientele was consistent with the demographics of the area. (*Id.* at 8.)

During the site visit, investigators were required to interview the appropriate personnel and to complete the data collection worksheet. (*Id.* at 7, 9.) Investigators were instructed to use the data collection worksheet as a guide and to be generally observant and particularly watchful for potential indicators of diversion, including: customers exhibiting drug-seeking behaviors; cars full of pharmacy customers; out-of-state license plates in the parking lot; long lines at the pharmacy; customers who appear to be from outside the reasonable drawing area for the facility;

[26] Revised versions of these SOPs were issued in November 2009, April 2012, and June 2012.

evidence of illicit drug use around the facility (e.g., used syringes, empty prescription containers); mailing materials or other evidence of operation of an internet pharmacy; high ratio of prescriptions for regulated drugs versus other drugs; high ratio of regulated prescription drug stock to other prescription drug stock; small or non-existent front end (non-prescription) drug stock; and primarily cash transactions for regulated drug prescriptions.[27] (*See id.* at 7-8.) Investigators were expected to request a tour of all areas of the facility and permission to take photographs of the front of the prescription department, the front end non-prescription drug sections, several prescription bays or shelves, the back room, any automation, and the front of the facility from the outside. (*Id.* at 9-10.) Investigators were also directed to request a recent drug utilization report from the pharmacy, showing the top twenty-five controlled substances by quantity dispensed[28] and six to twelve months of usage data by month. (*Id.* at 10.)

Other important factors included: the volume of controlled substances ordered; the percentage of transactions that did not include some form of third-party payment; the percentage of Schedule II controlled substances dispensed relative to all controlled substances; the percentage of controlled substances dispensed relative to non-controlled substances; and whether the pharmacist seemed to understand his or her responsibility to dispense controlled substances only for legitimate purposes. (Feb. 6 Moné Decl. ¶ 21.)

During the report preparation phase, the investigator was directed to analyze the information collected, to formulate a recommendation to the Director of Investigations, and to prepare a final report in the pre-approved memo format. (On-Site Investigations, Dec. 22, 2008, at 11.) At a minimum, the report would indicate whether the pharmacy posed a significant risk of diversion. (*Id.*) In the usual case, a site visit was to be completed within thirty days of assignment and a final report was to be submitted to the Director of Investigations within ten days of the visit, but priority cases could be assigned shorter time frames. (*See id.* at 4.)

The SOPs required the Director of Investigations to "monitor the progress of cases and provide guidance and direction as necessary to develop and move the case to a successful conclusion." (*Id.* at 5.) The Director was required to "conduct a thorough, final review of each case and make a determination whether the case is complete … ." (*Id.* at 12.) Initially, the first Director of Investigations, Steve Morse, reviewed every site visit report, but he later required the investigators to rate each customer as a high, medium, or low risk of diversion, and then he reviewed customers that the investigators identified as medium or high risk. If an on-site investigation was conducted in response to a threshold event, Morse, a pharmacist, would usually make the decision whether to adjust the customer's threshold.

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[27] Revised SOPs issued in November 2009 included four additional factors: one employee responsible for ordering, monitoring, and invoicing products; a high number of customers compared to their peers; for practitioner offices, whether the practitioner dispensed directly to the public; and a lack of auditing processes surrounding the purchases. (On-Site Investigations, Nov. 5, 2009, at 7.)

[28] Revised SOPs issued in November 2009 required drug utilization reports showing all controlled substances by quantity dispensed or administered. (On-Site Investigations, Nov. 5, 2009, at 8-9.)

c. Reporting Suspicious Orders

The CSA requires distributors to "design and operate a system to disclose . . . suspicious orders of controlled substances" and inform the appropriate DEA Field Division Office of any suspicious orders. 21 C.F.R. § 1301.74(b). According to the § 1301.74(b), "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). The Company issued SOPs and conducted training in December 2008, explaining the obligation to report suspicious orders and providing the definition of suspicious orders set out in C.F.R. § 1301. (Regulatory Notification of Suspicious Orders and/or Suspension of Sales of Scheduled /List 1 Substances (hereinafter, "Regulatory Notification"), Dec. 22, 2008, at 1; *see also* Joint Legal QRA Meeting, at 5.) The SOPs described the necessary information and provided form memos to be used in reporting suspicious orders to the DEA and State boards of pharmacy. (Regulatory Notification, at 4-8.) The pharmacists in the anti-diversion group determined which orders should be deleted and not filled and which customers to report to the DEA as suspicious based on the language of § 1301.74(b), and their knowledge and expertise.

4. Training

The Company provided anti-diversion training to distribution center employees, including all personnel with access to controlled substances and their supervisors, as well as the pharmaceutical sales force and any personnel involved in compliance-related functions. (Morford Decl. ¶ 8; Quintero Decl. ¶ 8.) The Company required thousands of employees across a variety of departments[29] to take the Anti-Diversion – Know Your Customer training module, which covered such topics as: types of diversion; the Company's approach to combating diversion and the purpose of the anti-diversion measures; reporting suspected violations; screening new customers; monitoring existing customers; investigating suspected diversion; and taking corrective action once diversion was detected. (*See* Anti-Diversion KYC WebX Training Module, at 8, 18-25, 28, 31, 35-37.) Employees were required to score 100% on the post-training test to earn a certificate of completion. (Anti-Diversion KYC Web-X Training Module, at 5.) The module was administered through the "MyLearning" program, which automatically assigned computer-based training to employees based on their job titles, and sent electronic notifications and reminders to employees about required training. Any training not completed by the due date would be included on a past due list and the employee's supervisor would be notified.

In addition to computer-based training, there were also periodic live presentations regarding the anti-diversion system. (*See, e.g.*, Supply Chain Integrity, Michael A. Moné, 2010 (discussing the SOM system and indicators of diversion); Quality and Regulatory Affairs: Overview of Anti-Diversion Program, 2011 (discussing the electronic monitoring system and KYC procedures).)

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[29] The departments included Sales (Medical and Pharmaceutical), Operations, Human Resources, Finance, Customer Service, IT, Facilities, and Real Estate.

a. Training of Sales Personnel

In addition to the Anti-Diversion Training Module, the sales force received supplementary training on the Know Your Customer procedures and the electronic monitoring system. (*See, e.g.*, Anti-Diversion: It's Everyone's Responsibility, Cardinal Health National Sales Conference Presentation, Michael A. Moné, 2008, at 3-5.) The salespeople were also trained on indicia of diversion, such as long lines in the pharmacy, out-of-state customers, and large percentages of controlled substance sales that were not reimbursed by insurance or other health programs. (Giacomin Decl. ¶¶ 9-10.) A ready reference document was provided to help salespeople identify signs of diversion.

The sales force received anti-diversion training from QRA and from their own dedicated training staff. Moné also spoke each year at the annual sales conference on compliance issues and trends in diversion. (Giacomin Decl. ¶ 9.)

b. Training of QRA Personnel

Pharmacists, investigators, analysts, distribution center employees, and compliance officers all received anti-diversion training focused on their specific job functions. Each of the pharmacists was trained on the Company's anti-diversion policies and procedures, including the procedures for reviewing customers and threshold events. Pharmacists also received "on-the-job" training focused on monitoring existing customers for signs of diversion.

The investigators received one-on-one training with the Director of Investigations when they started with Cardinal Health. Because the investigators already had investigative experience, the training focused on pharmacies and drugs, including warning signs to look for when evaluating a pharmacy, as well as different types of drugs and standard nomenclature. The investigators were also trained on the Company's anti-diversion system and procedures, and on setting the proper "tone" during site visits. In addition, the investigators and pharmacists attended conferences of the National Association of Drug Diversion Investigators ("NADDI"), the National Association of State Controlled Substances Authorities, and the American Pharmacists Association. (Feb. 6 Moné Decl. ¶ 5.)

Analysts received training that included how to interpret and verify information provided by customers and how to research and gather information on customers. Analysts also received instruction on the types of information that should be brought to the attention of their superiors in QRA.

Distribution center employees underwent extensive training on anti-diversion and other compliance-related issues. Employees in the cage and vault received additional anti-diversion training. All distribution center employees were provided with a wallet card listing indicators of diversion. Compliance officers were responsible for administering training on any relevant changes to the procedures, and would conduct periodic audits to ensure that all personnel had undergone the required training.

New compliance officers typically underwent week-long training at the Company's corporate offices, which included training on the anti-diversion policies and procedures.

Compliance officers also attended annual meetings at the corporate offices, where they received additional training on the Company's anti-diversion system. The topics discussed at the annual meetings included the relevant regulations and the obligation to report suspicious orders, the implementation of the electronic monitoring system and changes to the system, sample threshold event exercises, and trends in diversion, among others. (*See, e.g.*, DEA & Boards of Pharmacy Priorities, QRA Compliance Officer Annual Meeting, Michael A. Moné and Martha Russell, June 9, 2010; QRA – SOM Update 2011, Michael A. Moné, June 29, 2011.)

5. DEA Inspections

As part of the 2008 MOA, the DEA visited Cardinal Health headquarters in Dublin in early 2009 to review the new anti-diversion system, and conducted "compliance reviews" at five distribution centers. (*See* 2008 MOA at 5-6.) The DEA indicated initially that it found the controls in place at one distribution center, the facility located in Valencia, California, to be "unsatisfactory," but the Company rectified the issues and the DEA did not bring any formal proceedings regarding the facility. (*See* Letter from Larry P. Cote to Mark Hartman, Mar. 16, 2009; Letter from Jodi L. Avergun to Wendy H. Goggin and Larry P. Cote, Mar. 25, 2009; *see also* Chief Compliance Officer Q3 Update, Craig Morford, May 2009, at 4.)

The DEA also conducted routine cyclical inspections at Cardinal Health distribution centers in the years following the 2008 MOA. The DEA did not issue any negative findings regarding the anti-diversion measures in place at any distribution center in the years leading up to the October 25, 2011 Warrant for Inspection for the Lakeland facility.[30] In general, notes taken by Cardinal Health personnel who were present during the inspections indicated that the DEA inspectors were satisfied with the anti-diversion procedures that they reviewed. (*See generally,* DEA Cyclical Inspection Notes.) These notes were forwarded to management within QRA, and the Company informed the Board that the inspections had been "successful" and that there were no negative findings regarding the SOM system. *See infra* Part V.

For example, during the May 2009 inspection of the Aurora, Illinois facility, Cardinal Health personnel reviewed the SOM system with the DEA inspectors and the list of "red flags" used when reviewing orders. (DEA Cyclical Inspection Notes, at 3.) Notes taken by a Cardinal Health employee who was present during the inspection state that the DEA inspectors told facility personnel during the exit interview to "keep up the good work." (*Id.*) In an email to a Vice President of QRA regarding the final day of the inspection, a regional director who was present for the inspection noted, "[w]e heard from them during the closeout many many times 'We have nothing for you, you guys are perfect.'" (*Id.* at 2.) Similarly, during the August 2010 inspection of the Knoxville, Tennessee facility, during which the facility's compliance officer

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[30] In September 2009, the DEA conducted a cyclical inspection of the distribution center located in Hudson, Wisconsin. (*See generally*, DEA Cyclical Inspection Notes, at 33-37.) The inspectors commented during the inspection that certain orders that the Hudson facility filled should have been reported as suspicious, but there were no negative findings issued and, according to the notes from the inspection, the inspectors indicated that they were generally satisfied with the inspection. *Id.* at 37.

In Fall 2011, the DEA sent letters of admonition regarding certain operational compliance issues for three facilities, relating specifically to record keeping and the fact that one facility shipped controlled substances to a customer's new address that had not yet been registered with the DEA.

gave a short explanation of the Company's "identify, block, report" mantra for suspicious orders, one of the inspectors remarked during the exit interview, "'everything is peachy.'" (*Id.* at 29.)

In May 2010, two DEA field inspectors conducted a two-day inspection of the Company's Lakeland, Florida distribution center.[31] (*Id.* at 18.) The inspection included a review of the facility's security system, ARCOS/CSOS[32] protocol, specific customer order history, inventory reports and records, and anti-diversion training. (*Id.* at 18-19.) The distribution center personnel also gave a presentation to the DEA inspectors on the SOM system, which lasted over an hour and included a power point presentation. (DEA Cyclical Inspection Notes, at 18; Butler Decl. ¶ 19.) The DEA inspectors stated that they needed to see the SOM system in action because a major purpose of the inspection was "to ensure that Cardinal Health was doing what they had agreed to in the [2008] MOA and that the process was working the way they said it did." (*Id.*) The inspectors asked to review the SOM process from account set-up to deactivation, including examples of all documents and forms used during the process, for seven specific customers. (*Id.* at 19.)

During the review of the seven customers, facility personnel provided the inspectors with the Schedule II and Schedule III controlled substance sales for those customers for a two-month period, noting that the Company had previously discontinued controlled shipments to one of the registrants in September 2009. (*Id.* at 19.) The DEA inspector reviewed the documentation for this particular customer, continually noting that reviewing the specific records and documentation would verify whether the SOM system was working. (*Id.*) According to the notes recorded by a Company employee, the DEA inspector indicated that "[t]he documentation reviewed verified the process was working as presented." (*Id.*)

The inspection also reviewed the facility personnel's knowledge of the ARCOS and CSOS systems. (*Id.* at 18.) Although the ARCOS/CSOS portion of the inspection was a new component not previously reviewed by DEA, the notes indicate that the inspectors were impressed with the employees' knowledge of the relevant process. (*Id.* at 18, 20.)

During the final portion of the inspection, the inspectors asked the distribution center Compliance Officer about the various training efforts for employees. (*Id.* at 20.) The Compliance Officer noted that everyone who worked in the facility was required to undergo training that included "DEA general awareness, anti-diversion, and suspicious order monitoring," and that employees who had unsupervised access to the cage/vault area were required to complete Cage/Vault certification training and score 100% on the post-training test.

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[31] The DEA also visited the Lakeland facility in early 2009, in accordance with the 2008 MOA. Personnel who were present for the inspection, including a Regional Director of Quality, reported that the DEA agents complimented the facility's systems, and that no changes needed to be made in response to the inspection.

[32] ARCOS stands for Automation of Reports and Consolidated Orders System and is a system used by DEA and other governmental authorities to gather information from drug manufacturers and distributors regarding inventories, acquisitions, and dispositions of controlled substances. (*See* http://www.deadiversion.usdoj.gov/arcos/faq.htm.) CSOS stands for Controlled Substance Ordering System and is a DEA program that allows for electronic ordering of controlled substances. (*See* http://www.deaecom.gov/about.html.)

(*Id.*) The DEA inspector seemed surprised and impressed to learn that a 100% score was required. (*Id.*; Butler Decl. ¶ 18.) The DEA inspector also seemed surprised to learn that there was mandatory annual follow-up training on the cage/vault certification, SOM system, anti-diversion and DEA general awareness. (*Id.*)

At the end of the inspection, the DEA inspectors advised facility personnel that their inspection resulted in no negative findings or comments and that the Lakeland facility was in compliance with DEA regulations and the terms of the MOA. (Butler Decl. ¶ 22; DEA Cyclical Inspection Notes, at 20.) The inspectors indicated that the SOM presentation was "great" and that they were able to verify actual compliance by tracing customer activity through account set up to deactivation. (DEA Cyclical Inspection Notes, at 20.)

In July 2009, the DEA conducted an inspection of a distribution center in Peabody, Massachusetts. The inspector suggested to facility personnel, and then to Moné via telephone, that Cardinal Health should conduct due diligence on chain stores in the same manner as it did for independent pharmacies, including by conducting site visits of chain stores.[33] (*See* Declaration of Joseph Rannazzisi, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 10, 2012), ¶ 59.) Soon after, Moné spoke with Barbara Boockholdt, Chief of the Regulatory Section in the DEA's Office of Diversion Control, and relayed the conversation with the inspector and reminded Boockholdt that Cardinal Health coordinated with the chain pharmacies' corporate loss prevention departments regarding orders of concern and did not conduct on-site investigations of chain pharmacies.[34] (Apr. 23 Moné Decl. ¶ 8.) Based on the fact that Boockholdt made no disagreement and on his prior experiences with Boockholdt, Moné concluded that the DEA did not object to Cardinal Health's procedures for chain pharmacies. (Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 20, 2012) ("Feb. 20 Moné Decl."), ¶ 15.) In November 2009, Boockholdt indicated that Cardinal Health should exercise the same level of oversight with respect to chain pharmacies as it did with independent pharmacies. (Apr. 23 Moné Decl. ¶ 9.) The Company explained its method of coordinating its diligence efforts with the chains' loss prevention teams in addition to conducting its own review of the ordering data for chain stores, and there were no further comments from the DEA about the issue. (*Id.*)

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[33] The inspector also commented on the fact that records for certain chain pharmacies were not available at the facility, and Moné explained to the inspector that such records are maintained at Cardinal Health's headquarters in Dublin. (Supplemental Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 12, 2012) ("Feb. 12 Moné Decl."), ¶ 7.)

[34] Moné had previously discussed this with Boockholdt during the DEA visit to Cardinal Health's headquarters in Dublin in early 2009, and neither Boockholdt nor any of the other DEA personnel present during that meeting raised any objections to the Company's procedures for chain pharmacies. (Supplemental Declaration of Michael A. Moné Pursuant to 28 U.S.C. § 1746, *In re Cardinal Health*, No. 12-32 (DEA ALJ Apr. 23, 2012) ("Apr. 23 Moné Decl."), ¶ 3.)

V. COMMUNICATIONS WITH THE BOARD AND AUDIT COMMITTEE REGARDING ANTI-DIVERSION MEASURES

The Board and Audit Committee[35] received regular and extensive updates regarding the anti-diversion system. Craig Morford provided annual compliance reports to the Board each August and annual regulatory reports to the Audit Committee (or the full Board) each November. Morford also provided the Audit Committee and the Board with updates on compliance and regulatory issues as warranted, either at the quarterly meetings or via communications between the quarterly meetings.[36] The Board was also provided with updates as part of the Company's Enterprise Risk Management system, which informs the Board about risks the Company is facing, including enforcement actions and compliance issues. (*See, e.g.*, Enterprise Risk List, May 2011.) In addition, Morford updated the Audit Committee and the Board on an as-needed basis.[37] The following is a summary of some specific communications and materials relating to the Company's anti-diversion measures that were provided to the Board and the Audit Committee between 2007 and 2012.

In August 2007, Walsh provided the Board with a presentation that highlighted the creation of the anti-diversion policies. (Annual Program Review, Ethics and Compliance, Dan Walsh, Aug. 2007, at 4.) Two months later, the Audit Committee received a report listing issues and initiatives for 2007, including reengineering systems and updating practices for controlling Schedule 3 drugs. (Quality & Regulatory Affairs Update, Gary Dolch, Oct. 2007, at 6.) In November 2007, the Audit Committee was informed that the Company had developed a web-based training module and administered anti-diversion training to more than 2,300 employees. (Chief Ethics and Compliance Officer Update, Daniel J. Walsh, Nov. 6, 2007, at 3, 6.)

In January 2008, the Audit Committee learned that the Company engaged "outside counsel and their retained anti-diversion experts to conduct an expansive review of the historic and current anti-diversion practices at all of the Company's distribution facilities." (Report on Lawsuits and Claims, Ivan K. Fong, Jan. 18, 2008, at 7.) In addition, the Audit Committee learned that the Company had accelerated the due diligence being performed on customers that were top purchasers of certain controlled substances, established ordering limitations for those substances, and began implementation of a computerized order monitoring and control system to assist in preventing diversion. (*Id.*)

In advance of the January 31, 2008 Board meeting, the Board was informed that in reacting to the "flurry of actions from the DEA," the Company took immediate action against a

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[35] The Audit Committee is appointed by the Board to assist the Board with, among other things, the Company's compliance with legal and regulatory requirements and the Company's processes for assessing and managing risk. (*See* Audit Committee Charter, Nov. 2, 2012, at 1.) The Audit Committee meets as often as it deems necessary, but is required to meet at least once per quarter. (*Id.*)

[36] Before Morford joined the Company, the Board received compliance and regulatory updates from his predecessor, Daniel Walsh, as well as Ivan Fong, the Chief Legal Officer and Secretary, and Jeff Henderson, the Chief Financial Officer.

[37] When a new director joined the Board, Morford and Steve Falk, General Counsel, would provide that director with an overview of the Company's anti-diversion program. Gilberto Quintero also provided updates to the Board, and provided the Board with an overview of the entire anti-diversion system.

number of pharmacies that were flagged as suspicious based on their ordering patterns or other factors. (Controlled Substance Diversion Update, Jeff Henderson, Jan. 23, 2008, at 2.) As a result, the Company ceased distributing to a number of suspicious pharmacies, but also temporarily cut off a few customers that further investigation showed to be potentially legitimate. (*Id.*) The Board was also provided with a detailed action plan for the Company's key anti-diversion measures in the form of a seven-page chart listing the tasks to be completed, the progress thus far, and target completion dates. (*Id.*) The progress included changes to the anti-diversion personnel, processes, and systems, including: hiring additional anti-diversion personnel and reorganizing the anti-diversion group; improving the reviewing and reporting structure; revising certain procedures relating to investigations, communication between departments, and monitoring; and developing enhanced anti-diversion training. (*Id.*)

The Board was also provided with a presentation listing the key anti-diversion measures that had been implemented or were in the process of being implemented. (DEA Update, Jeff Henderson and Ivan Fong, Jan. 31, 2008, at 4.) These measures included the development of heightened criteria for new customers, development and implementation of enhanced training, organizational realignment and hiring of new anti-diversion personnel, conducting investigations on hundreds of existing customers and utilizing outside investigators as needed, launching the IT solution for order review, initiating independent, third-party review, suspending over sixty accounts, implementing order limits for certain drugs, and revising the sales compensation structure to encourage salespeople to report signs of diversion. (*Id.*) The Company also indicated that it was focused on responding promptly to any indicators of diversion ("red flags") and suspicious orders, and maintaining a dialogue with the DEA regarding the new IT system. (*Id.* at 5.)

In February 2008, Fong and Henderson provided an update to the Board highlighting key changes in the anti-diversion system that had already been implemented based on recommendations of outside counsel and other anti-diversion consultants, in the areas of personnel, processes, training, and systems. (Anti-Diversion Update, Ivan K. Fong and Jeff Henderson, Feb. 22, 2008, at 3-4.) These changes included hiring new anti-diversion leadership, reviewing and replacing QRA personnel at distribution centers, and hiring a team of investigators. (*Id.* at 3.) In addition, the Company established procedures to review threshold events, approve new customers, and improve communications between the Sales and QRA teams. (*Id.* at 3.) As a result of these new processes, the Company terminated over 110 customers and rejected six potential new customers. (*Id.* at 4.) Further, the Company initiated comprehensive and ongoing anti-diversion training and continued to roll out the electronic order monitoring system. (*Id.* at 3-4.)

During the May 7, 2008 Board meeting, Fong and Henderson provided the Board with another update describing the progress on key anti-diversion action items, which included the hiring of a Chief Compliance Officer, a Senior Vice President of Supply Chain Integrity, a Vice President, two directors, six investigators, and twenty-four field QRA compliance managers, as well as the implementation of new procedures, training, and an enhanced electronic monitoring system for retail independent pharmacies. (Anti-Diversion Update, Ivan K. Fong and Jeff Henderson, May 7, 2008, at 2.)

The May 2008 presentation also described the Company's newly-established standardized criteria to identify excessive purchases, and its enhanced process for investigating suspicious orders. (Anti-Diversion Update, Ivan K. Fong and Jeff Henderson, May 7, 2008, at 5.) As part of these improvements, the Company conducted site visits of 266 customers, and twenty-one distribution centers, and implemented recommendations made by outside counsel for each. (*Id.*) Further, the Company stopped selling to, and reported, 115 customers. (*Id.*) The Company also completed the first two phases of implementing the electronic monitoring system, which involved refining the thresholds for retail independent pharmacies, and rolling out the remaining classes of trade. (*Id.* at 6.) As a result, from January through March, the Company blocked and investigated 2,760 excessive orders. (*Id.* at 6.) Other improvements to the Company's anti-diversion measures included: the development of educational materials for employees regarding diversion and controlled substance abuse; the establishment of more focused communications between sales, operations, and QRA; the performance of distribution center QRA process and procedural audits relating to controlled substance handling and security; review of the relevant SOPs with QRA personnel; training of 1,700 employees at over 100 different training events; and development and implementation of an on-going training curriculum. (*Id.* at 5.) The presentation included a list of items to be completed in the short-term, which included upgrading the SOPs, completing full implementation of the electronic monitoring system, fully training personnel on anti-diversion requirements and KYC policies, and enhancing the distribution center level security and in-transit processes. (*Id.* at 2.)

Shortly after the May 2008 Board meeting, Fong informed the Board about an investigation by the Ohio Board of Pharmacy, based on allegations that the Company's distribution center in Findlay, Ohio made suspicious sales to a pharmacy in Dublin from December 2006 through March 2007. (Email from Ivan Fong to Cardinal Health Directors, May 29, 2008.) Fong relayed that anti-diversion personnel noticed the increased orders of controlled substances for that pharmacy in February 2007. (*Id.*) The Company conducted a site visit in March 2007 and terminated the customer in April 2007, a few days after the Ohio Board of Pharmacy suspended the customer's license. (*Id.*) Fong communicated the belief that the current anti-diversion controls would have caught the suspicious behavior of this pharmacy much sooner. (*Id.*)

In advance of the August 5, 2008 Audit Committee meeting, Morford provided the Audit Committee with his first Chief Compliance Officer Update, which noted that the role of Chief Compliance Officer had been greatly expanded and described the Company's current procedures for detecting suspicious orders of controlled substances. (Chief Compliance Officer Update, Craig Morford, Aug. 2008, at 2, 10.) This report also noted key accomplishments, including: establishment and implementation of the electronic monitoring system; establishment of the KYC program; KYC training administered to 2,500 employees; and the creation of thirty-eight new anti-diversion positions. (*Id.* at 10.) Finally, the report noted that key priorities for 2009 included rolling out the electronic monitoring system to the remaining classes of trade, finalizing a settlement agreement with the DEA, and bringing the suspended facilities back on line. (*Id.* at 11.)

Morford also provided a Chief Compliance Officer report to the entire Board, which included a review of anti-diversion updates. (Chief Compliance Officer Report, Craig Morford, Aug. 2008.) Among the changes discussed were the expansion of Morford's role as Chief

Compliance Officer, and business leaders throughout the Company being given the "duty, responsibility, and accountability" for making appropriate decisions regarding quality and compliance. (*Id.* at 6.) The Board was also updated on the Company's progress in achieving its goal of establishing a "premier system for identifying, reporting, and blocking suspicious controlled pharmaceutical orders." (*Id.* at 5.) Finally, Morford noted that expanding the electronic monitoring system and establishing sufficient systems to comply with the forthcoming settlement with the DEA were top priorities. (*Id.* at 10.)

In November 2008, Morford informed the Audit Committee that the Company had reached a settlement with the DEA, and explained the Company's obligations under the settlement agreement. (Chief Compliance Officer Q1 Update, Craig Morford, Nov. 2008, at 9, 20-21.) The Audit Committee also learned that training on the KYC procedures and the implementation of those procedures was complete and, as of the end of October 2008, the electronic monitoring system covered 80% of DEA registrants. (*Id.* at 9.) The Company expected to complete the roll out of the electronic monitoring system across the remaining classes of trade by December 2008. (*Id.*) Morford also informed the Audit Committee that DEA compliance inspections were scheduled to begin in January 2009. (*Id.*) To prepare for these inspections, the Company planned to revise and develop SOPs to improve the existing supply chain integrity process. (*Id.*) The Audit Committee was also informed that anti-diversion training was in progress on distribution center and sales SOPs, KYC procedures, and the electronic monitoring system. (*Id.* at 19.) Fong also discussed the DEA settlement and the Company's anti-diversion measures at the next day's Board meeting.

The Audit Committee received another update on the anti-diversion measures in February 2009, including that the electronic monitoring program was rolled out to the additional classes beyond retail independent pharmacies, and that the program was favorably received by the DEA on December 18, 2008. (Chief Compliance Officer Q2 Update, Craig Morford, Feb. 2009, at 12.) The materials also stated that the distribution centers that had been suspended in 2007 and 2008 were back online and that, as part of the settlement with the DEA, the DEA planned to conduct compliance reviews at the Company's corporate headquarters and at several facilities. (*Id.*)

The Audit Committee received an update regarding the DEA inspections in advance of its May 2009 meeting. (Report on Lawsuits and Claims, Stephen T. Falk, Apr. 23, 2009, at 10.) The Audit Committee was informed that in January and February 2009, the DEA had visited the Company's Dublin headquarters and performed compliance reviews of five distribution centers. (*Id.*; *see also* Chief Compliance Officer Q3 Update, Craig Morford, May 2009, at 4.) Further, the Audit Committee was informed that on March 16, 2009, the DEA notified the Company that it considered one of those distribution centers, the facility located in Valencia, California, to be "unsatisfactory," and that the Company met with the DEA to address those concerns on March 19 and submitted a written response to the DEA on March 25. (Report on Lawsuits and Claims, Steve Falk, Apr. 23, 2009, at 10.) In May 2009, Morford informed the Audit Committee that the Company received favorable oral feedback regarding the Valencia facility issues. (Chief Compliance Officer Q3 Update, Craig Morford, May 2009, at 4.)

In August 2009, Morford informed the Audit Committee that the Company completed data reviews for all customers and all necessary customer investigations, and achieved "superior

results" on routine DEA cyclical inspections of five distribution centers. (Chief Compliance Officer Q4 Update, Craig Morford, Aug. 2009, at 4.) Morford also provided an update on the Company's anti-diversion efforts to the entire Board. (Annual Compliance Program Review, Craig Morford, Aug. 2009.) The update stated that the Company had "[d]esigned and implemented an effective Suspicious Order Monitoring Program across all classes of trade," successfully completed routine DEA cyclical inspections of five distribution centers with "superior ratings," and developed regulatory operations SOPs. (*Id.* at 5.) The Board was also informed that 3,600 employees underwent anti-diversion training during fiscal year 2009.[38] (*Id.* at 22.) In October 2009, the Audit Committee received a compliance update noting that the routine DEA cyclical reviews of distribution centers to date had "gone well." (Quarterly Compliance Program Update, Craig Morford, Oct. 27, 2009, attaching Compliance: Quarterly Compliance Program Update, Craig Morford, Nov. 2009, at 2.)

In October 2010, Morford provided the Audit Committee with an Annual Quality and Regulatory Report, which included an overview of the then-current regulatory environment. (2010 Annual Quality and Regulatory Report, Craig Morford, Oct. 2010, at 4-5.) Morford noted that the DEA had increased its focus in "high risk" states, including Florida. (*Id.* at 4.) The expected areas of focus for the DEA were dispensing pain clinics, selected pharmacies servicing non-dispensing pain clinics, and distributors servicing "bad" pharmacies. (*Id.*) In response to the increased focus in Florida, a task force was assigned to evaluate all Florida customers, and work with customers to address potential diversion risks and/or terminate customers that posed too high of a risk. (*Id.* at 8.) During the ensuing months, the Company expected the DEA to focus on the Company's operational controls and the overall effectiveness of its anti-diversion program. (*Id.* at 4.) The report also noted that the DEA had conducted twenty-five routine cyclical inspections over the previous twelve months, which resulted in no "observations," or negative findings. (*Id.* at 7, 10.)

Morford provided the full Board with a review of the main anti-diversion risks in advance of the November 2010 Board meeting. (Review of Key Risks – November Board Meeting, Craig Morford, Oct. 26, 2010, attaching Enterprise Risk List, Nov. 2010.) He also noted the ways those risks were being mitigated, including: the electronic monitoring program, which was overseen by experienced pharmacists; the KYC procedures; the advanced analytics driving focused customer visits; the focused approach in high risk areas, such as Florida; the plans for business continuity; and the continued monitoring of DEA meetings. (Enterprise Risk List, Nov. 2010, at 1, 7.)

On July 26, 2011, Morford sent a memorandum to the Board regarding key initiatives and accomplishments in fiscal year 2011. (Pre-read for Key Risks and Annual Compliance Review, Craig Morford, July 26, 2011.) Among other things, the memorandum described the enhanced electronic monitoring system, which decreased "false positives," i.e., legitimate customers or

[38] The training efforts continued, and in July 2010, the Directors were informed that anti-diversion training had been administered to many additional employees. (Annual Update – FY '10, Ethics and Compliance Program, Craig Morford, July 27, 2010, at 3.)

orders that were flagged as suspicious.[39] (*Id.* at 5.) On the same day, the Board also received a memorandum from Morford and Falk regarding a customer who wanted to do business with Cardinal Health and was upset that the Company had refused, based on a determination that the pharmacy posed a high risk of diversion. (Communication from Pharmacy Owner, Craig Morford and Steve Falk, July 26, 2011.)

In advance of the November 2011 Board meeting, Morford and Quintero provided an update on regulatory matters, including the regulatory environment and increased focus on distributors. (Annual Quality and Regulatory Report, Craig S. Morford, Oct. 25, 2011, at 2-3.) The update stated that the DEA conducted twelve routine cyclical inspections during fiscal years 2011 and 2012, which resulted in four "observations," or negative findings.[40] (*Id.* at 5.) The update also identified the risk of the DEA's aggressive posture on anti-diversion and the Company's major mitigating factors, including: the development of an advanced analytics program to better predict diversion; the formation of SWAT teams to evaluate high risk regions, including Florida; the hiring of former DEA senior counsel as a consultant to the Company; and close coordination of senior business leaders in managing risk. (*Id.* at 6.) Further, the update discussed key accomplishments in the Company's anti-diversion program during fiscal year 2011. (*Id.* at 10.) In particular, the Company underwent five successful DEA cyclical inspections and the DEA had not issued any findings regarding the SOM system for the previous three years. (*Id.*) The update also stated that the Company had reduced impact to legitimate customers by increasing accuracy through advanced analytics, including the introduction of a new model to predict the probability of a customer engaging in diversion. (*Id.*) As a result, the incidence of flagged events was reduced by 2,509, or 37%, from fiscal year 2010 to 2011. (*Id.*) Additionally, during fiscal year 2011, forty-seven suspicious orders were identified and reported to the DEA, thirty-six customers were restricted from purchasing controlled substances, and eighteen potential new customers were denied from purchasing controlled substances. (*Id.* at 10-11.)

A separate report prepared for the November 2011 Board meeting further discussed the regulatory risks posed by the DEA's aggressive posture and noted that the Lakeland distribution center received an investigational warrant on Oct. 26, 2011. (*See generally*, 2011 Annual Quality and Regulatory Report – Pharma Segment, Craig Morford and Gilberto Quintero, Nov. 2, 2011.) The report included a summary of the Company's anti-diversion initiatives over the last four years, including the use of statistics and advanced analytics to help make determinations regarding customer risk, noting that the Company had made significant monetary investments in the new system and engaged many additional employees. (*Id.* at 5.) The report noted that since 2007, over 300 pharmacies had been terminated and reported to the DEA as suspicious, and fifty of those were in Florida.[41] (*Id.*)

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[39] The prior system resulted in many more "false positives" and legitimate customers being terminated as diversion risks. The Company implemented changes in 2011 that refined the electronic monitoring system and increased its accuracy.

[40] *See supra* note 30 (discussing the letters of admonition addressing operational compliance concerns).

[41] In addition to the updates discussed above, the Board and Audit Committee also received updates regarding compliance issues and the status of the Company's anti-diversion efforts at the following

VI. THE 2012 ISO

A. The Events Surrounding the 2012 ISO

The 2012 ISO asserted that from January 2008 through December 2011, Cardinal Health sold excessive amounts of oxycodone to its top four retail pharmacy customers, all located in Florida and serviced by the Company's Lakeland facility: two CVS stores, CVS/Pharmacy #00219 ("CVS 219") and CVS/Pharmacy #05195 ("CVS 5195"), and two independent retail pharmacies, Caremed Health Corporation ("Caremed") and Gulf Coast Pharmacy ("Gulf Coast").[42] (2012 ISO at 2.) The 2012 ISO alleged further that Cardinal Health "failed to conduct meaningful due diligence" of its retail pharmacy customers, including its chain customers, and "failed to detect and report suspicious orders of oxycodone products by its pharmacy customers."[43] (*Id.* at 3.)

The Company's electronic monitoring system flagged the four pharmacies at issue in the 2012 ISO, and the anti-diversion group reviewed the pharmacies' orders and communicated with the pharmacists at Caremed and Gulf Coast and with the CVS loss prevention department. Cardinal Health ceased distributing controlled substances to Caremed and Gulf Coast months before the 2012 ISO, and the quantity of oxycodone being shipped to CVS 219 and CVS 5195 had diminished significantly by that time.

With respect to Gulf Coast, Company personnel conducted frequent site visits, including in August 2008, April 2009, December 2009, October 2010, and February 2011. (Apr. 13 Moné Decl. ¶ 59.) Gulf Coast was located in a hospital medical complex and served emergency room patients, four pain management clinics, and three nursing homes and assisted living facilities, making the high volumes seem reasonable. (Feb. 6 Moné Decl. ¶ 43.b.) Further, in 2009, the hospital added over 300 beds. (Feb. 6 Moné Decl. ¶ 43.c.) The pharmacy provided drug utilization reports for December 2009 and July 2010, which the anti-diversion group reviewed and concluded were consistent with legitimate use. (Feb. 6 Moné Decl. ¶ 43.e.)

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meetings: the May 6, 2009 Board meeting; the January 31 and February 1, 2011 Audit Committee meeting; the May 3, 2011 Audit Committee Meeting; and the October 25, 2011 Audit Committee Meeting.

[42] According to the ISO, the amount of oxycodone that the Company was distributing to these pharmacies "well exceeded" the average amount of oxycodone that the Company's Florida retail pharmacies were receiving. (2012 ISO at 2.) The affidavit in support of the Administrative Inspection Warrant served on the Lakeland facility on October 26, 2011 also relied heavily on volume and comparison of sales averages. (*See* Affidavit for Administrative Inspection Warrant, Oct. 25, 2011, ¶¶ 5-6.) However, according to the DEA's own data, the average number of dosage units of oxycodone distributed from the Company's Lakeland facility to each of Cardinal Health's Florida pharmacy customers was far less than the average amount purchased by Florida pharmacies from late 2008 through 2011. (*See* Plaintiff Cardinal Health, Inc.'s Notice of Submission Pursuant to the Court's Order of February 16, 2012, at 6, *Cardinal Health, Inc. v. Holder*, No. 12-185 (D.D.C. Feb. 20, 2012) (including chart titled "Oxycodone Dosage Units Purchased by Pharmacies").)

[43] This section provides a brief summary of the events at issue in the 2012 ISO. A more detailed review of the DEA's allegations can be found in the Leonhart Declaration.

During an investigation in April 2009, the investigator, Vincent Moellering, learned some information about Gulf Coast from one of its competitors that caused him to question the pharmacy's orders. (*See* Feb. 6 Moné Decl. ¶ 43.a.) Although Moellering could not substantiate the information, and did not observe any other indicia of diversion, he called a local DEA agent and relayed the information. (Memorandum from Vincent Moellering to File re: Gulf Coast Medical Pharmacy, May 7, 2009, at 6.) Moellering did not hear back from the agent after that conversation. (Apr. 13 Moné Decl. ¶ 64.) The following year, after another site visit, Moellering rated Gulf Coast as a "high risk," and requested permission to contact the DEA regarding the pharmacy, because he was not "convinced that the owner [was] being forthright about his customer's [sic] origin or residence." (Report of Investigation re: Gulf Coast Medical Pharmacy, Vincent Moellering, Oct. 13, 2010, at 3; Apr. 13 Moné Decl. ¶ 64.) Moné told Moellering that the DEA did not have information regarding the addresses of the pharmacy's patients. (Apr. 13 Moné Decl. ¶ 64.) Moellering then contacted the pharmacy and requested a list of all physicians prescribing C2 – C5 drugs, and received a list of physicians in response. (Memorandum from Vince Moellering to File re: Gulf Coast Medical Pharmacy, Nov. 3, 2010.) Steve Morse, the Director of Investigations, determined that the information showed that "[t]he primary prescribers identified by the pharmacy owner [were] local, one exception being an orthopedic surgeon," and thus rated the pharmacy as a "medium risk." (Addendum to Report of Investigation dated 10/13/10 Gulf Coast Medical Pharmacy, Steve Morse, Nov. 9, 2010.)

In February 2011, Morse conducted a follow-up site visit of Gulf Coast and again rated the pharmacy as a "medium risk." (Report of Investigation re: Gulf Coast Medical Pharmacy, Steve Morse, Mar. 24, 2011.) However, in Fall 2011, Mallinckrodt, an oxycodone manufacturer, provided Cardinal Health with information indicating that Gulf Coast was purchasing oxycodone from other wholesalers in addition to Cardinal Health. (Apr. 13 Moné Decl. ¶ 69.) In addition, Gulf Coast was unable to verify its claim that the local Sheriff's Office supported the consolidation of prescriptions from four nearby health facilities through Gulf Coast. (*Id.* ¶ 70.) As a result, the Company terminated Gulf Coast on October 5, 2011. (*See* Feb. 6 Moné Decl. ¶ 43.f.)

The Company also conducted site visits and obtained drug usage reports for Caremed. (Feb. 6 Moné Decl. ¶ 44.) Caremed was located in a community health center with over one hundred doctors' offices, and served a sizeable elderly population. (Feb. 6 Moné Decl. ¶ 44.a.) Health centers typically offer varied treatment, including pain management. Caremed experienced threshold events in February and March 2010. (Apr. 13 Moné Decl. ¶ 52.) Morse communicated with Caremed's pharmacist, who explained that the pharmacy was experiencing growth due to a number of factors and provided a drug dispensing report. (Apr. 13 Moné Decl. ¶ 52.) Morse raised the threshold for Caremed in response. (Apr. 13 Moné Decl. ¶ 52.) In May 2010, an investigator performed a site visit of Caremed and concluded that the pharmacy posed a low risk of diversion because the significant elderly population in the surrounding area justified the volume of oxycodone prescriptions. (Apr. 13 Moné Decl. ¶ 53.) The pharmacy's monthly purchases of oxycodone increased between June and December 2010, and the Company sent an investigator to the pharmacy in January 2011. (Feb. 6 Moné Decl. ¶ 44.b.) The investigator again concluded that the pharmacy posed a low risk of diversion, based in part on the relatively low percentage of prescriptions that were paid for in cash. (Apr. 13 Moné Decl. ¶ 54.) However, Caremed again prompted concern in September 2011, when the drug utilization report showed a significant increase in the monthly prescriptions for oxycodone. (Feb. 6 Moné Decl. ¶

44.b.) When Moellering visited the store in September 2011, he learned that the physicians who were writing the prescriptions at issue were not located at the health center, and the Company thus terminated Caremed as a customer on September 26, 2011. (*See* Feb. 6 Moné Decl. ¶ 44.c.)

With respect to the CVS stores at issue in the 2012 ISO, the electronic monitoring system identified oxycodone ordering patterns for these stores that required explanation in late Summer and early Fall 2010. (Apr. 13 Moné Decl. ¶ 73.) In August 2010, Moné met with the Company's primary contact at CVS, Brian Whalen, about certain CVS stores that required investigation, including CVS 219. (Quintero Decl. ¶ 14; Apr. 13 Moné Decl. ¶ 73.) In September 2010, CVS informed the Company that their Loss Prevention team had reviewed the stores and had not uncovered any issues, and that the increase in sales for CVS 219 was due to the closing of other pharmacies in the area. (Quintero Decl. ¶ 14; Email from Paul Farley to Michael Moné re: CVS #0219, Sept. 30, 2010.) In October 2010, Christopher Forst, the Director of Pharmacy Assessment, visited CVS 219 without informing CVS and did not see any indicia of diversion. (Quintero Decl. ¶ 15; Email from Christopher Forst to Michael Moné re: CVS #219, Oct. 6, 2010.) Further, Moné concluded that the volumes of oxycodone being distributed to the two CVS stores did not appear unreasonable in light of the stores' large size, and the fact that they were located in busy suburban neighborhoods, and were open seven days per week. (Feb. 6 Moné Decl. ¶ 54.) Subsequently, in August 2011, the Company identified CVS 219 and 5195 as outliers and scheduled a meeting with CVS in late August, but the meeting was later rescheduled for October. (Quintero Decl. ¶¶ 21-22.) On October 12, 2011, in response to an email from Moné raising concerns about several CVS stores, including CVS 5195, CVS stated that CVS had conducted a comprehensive review and had not found any evidence of diversion. (Apr. 13 Moné Decl. ¶ 77; Quintero Decl. ¶ 22; Email from Karen Gibbs to Michael Moné re: Florida Stores, Oct. 12, 2011.)

On October 18, 2011, the DEA served warrants on CVS 219 and CVS 5195, and Cardinal Health lowered the oxycodone thresholds for these stores by significant amounts in November and December, respectively. (Apr. 13 Moné Decl. ¶ 78.) Further, in Fall 2011, CVS stopped filling prescriptions written by twenty-two Florida doctors. As a result, the Company's distribution of oxycodone to CVS 219 and 5195 fell drastically in November and December 2011. (Apr. 13 Moné Decl. ¶ 80.)

B. Reaction to the 2012 ISO

1. General Reactions Within the Company

In general, the reaction to the 2012 ISO was one of surprise and frustration, for a number of reasons.[44] First, the overall belief among management and within QRA was that the anti-diversion program was effective, and that the Company was meeting or exceeding its obligations. The DEA visited the Company's corporate headquarters in early 2009 and reviewed the new anti-diversion program. In addition, the DEA conducted at least twenty cyclical

[44] A February 15, 2012 email to the Board, sent on behalf of Falk, included a transcript of a investor call which expressed the Company's surprise and frustration with the 2012 ISO in light of the Company's extensive improvements to the anti-diversion systems since 2007. (Email from Steve Falk to Cardinal Health Directors, Feb. 15, 2012.)

inspections of Cardinal Health distribution centers from 2008 through 2011, and did not issue any negative findings regarding the anti-diversion measures in place at those facilities. Moreover, in 2010, the Company retained John Gilbert, an attorney who had previously served in the diversion section of the DEA's Office of Chief Counsel, to perform an independent assessment of the anti-diversion system. Gilbert recommended four changes to the system, and the Company implemented each of those changes. All of these factors contributed to the sense that the Company had been successful in building the anti-diversion system.

Second, before the 2012 ISO, the Company was operating under the impression that if the Company performed its diligence on customers, it could rely on the pharmacist's expertise and judgment in analyzing customers and orders. However, the 2012 ISO was based almost entirely on the volumes that were shipped to the four pharmacies at issue, indicating that a shift needed to be made to viewing large volume orders as "per se" suspicious. Third, one of the difficulties the Company faces in detecting suspicious orders is a lack of information. HIPAA precludes pharmacies from sharing patient-specific information, including information about prescriptions, with distributors. Further, the DEA does not inform other distributors when one distributor terminates a customer, because it could be subject to civil liability for disclosing such information. The Company also is not privy to information regarding whether pharmacies are purchasing controlled substances from multiple distributors and the aggregate quantities of controlled substances purchased by pharmacies. (Morford Decl. ¶ 19.) Fourth, the Company had terminated the two retail independent pharmacies at issue in the 2012 ISO months before it was issued, and significantly reduced the quantities being shipped to the two CVS stores at issue.

There was also the impression among some in management that, in hindsight, Morse and Moné should have terminated the independent pharmacies at issue in the 2012 ISO sooner. However, the system functioned properly by flagging each of the pharmacies at issue, and Morse and Moné made the decisions not to terminate those pharmacies in good faith, after reviewing the pharmacies and orders at issue.

In response to the 2012 ISO, the Company has attempted to reduce subjectivity in the system, and implement more objective criteria and procedures for reviewing pharmacies and orders. The view within management is that although there were good controls in place before the 2012 ISO, the Company has had to adjust certain measures to bring them in line with the current state of anti-diversion.

2. Modifications to Anti-Diversion Policies and Procedures

a. Personnel

In the months following the 2012 ISO, Moné was moved from his position as Vice President of Anti-Diversion into a position as attorney in the regulatory group, focusing on such things as training, policy development, and the Company's outreach efforts with boards of pharmacy. Moné continues to be recognized for implementing many effective anti-diversion measures, and possessing valuable knowledge and expertise. However, under Moné, the evaluation of customers and orders had been heavily focused on the clinical expertise and subjective judgment of the pharmacists in the anti-diversion group. The goal after the 2012 ISO

was to move towards assessing customers based more on objective criteria and a practical knowledge about the business.

Morse was moved from his position as Director of Investigations to a position in regulatory management, outside the arena of controlled substance anti-diversion. The view was that Morse was not as strategic as his former position required and there were questions about his judgment. Specifically with respect to the pharmacies at issue in the 2012 ISO, management felt that Morse should have reviewed Gulf Coast more thoroughly.

b. Monitoring Customers

The Company has continued its efforts to enhance the electronic monitoring system. In or around September 2012, the system moved to a linear regression model, which uses volume as a dependent variable and other factors as independent variables.

As a result of the Memorandum of Agreement entered into with the DEA in 2012 (the "2012 MOA"), the Company has also made changes to the policies with respect to adjusting thresholds. The 2012 MOA requires a "two-person concurrence . . . before increasing thresholds for higher volume customers for specific drug classes." (2012 MOA at 3.) In general, there has been a concerted effort to treat threshold events more consistently and objectively. The review of thresholds is less of a subjective analysis based on the customers' ordering history and more focused on how the customers' prescription drug count compares with the national average. Accordingly, the analysts in Rausch's group are now responsible for responding to threshold events. Analysts will adjust thresholds in a limited set of circumstances, by applying objective, numerical criteria. Generally, if a pharmacy exceeds its threshold and the pharmacy or order does not fall within those limited circumstances in which an analyst can adjust the threshold and release the order, the order will not be filled and will be reported to the DEA as suspicious.

Pharmacists are responsible for responding to threshold events for long term care and hospital pharmacies, which do not lend themselves to the objective criteria applicable to retail pharmacies. Pharmacists are also responsible for continually reviewing the largest volume customers. In addition, the Company created a Large Volume-Tactical and Analytical Committee ("LV-TAC") in response to the 2012 MOA, to review "higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida." (2012 MOA at 3.) LV-TAC holds monthly meetings and is comprised of numerous members across various departments. (*See* 2012 MOA at 3.)

During 2012, the salespeople started receiving additional information about their customers' ordering within a program called "Winwatcher," a tool designed to help the salespeople track their customers and sales goals, among other functions. Winwatcher notifies salespeople when a customer's percentage of accrual of its threshold amount (for any controlled substance or listed chemical that is assigned a threshold) surpasses the percentage of completion for the month (e.g., a customer reaches 60% of its threshold on the fifteenth of the month). Winwatcher always shows customers' percentage of accrual for oxycodone, hydrocodone, and alprazolam, regardless of the time of the month. Further, although investigators and pharmacists

at times conducted surveillance visits of chain stores before the 2012 ISO, it is now standard procedure for salespeople to conduct regular surveillance visits of chain pharmacies.[45]

c. On-Site Investigations

In or around March or April 2012, the report used by investigators in conducting site visits changed from Word documents to Excel documents. The new report is an interactive document that asks for specific, objective data, thereby removing a great deal of subjectivity from the investigation process. There has also been more standardization in the procedures for site visits, and additional investigators have been hired as part of a concerted effort to shorten the time for completing investigations. Additionally, in an effort to increase transparency among departments, there is more frequent communication between investigators, pharmacists, and salespeople, about specific pharmacies and about whether and when a site visit is going to be conducted.

Moreover, the current Director of Investigations now reviews each site visit report and makes a concerted effort to provide timely feedback and guidance. Despite the requirement in the SOPs issued in 2008 that the Director of Investigations review each site visit report, Morse did not do that.

d. Reporting Suspicious Orders

The prior approach to reporting suspicious orders to the DEA was to report an order as suspicious when the customer appeared suspicious, i.e., report an order that, after review, led the Company to terminate the customer as an unreasonable risk of diversion. The current approach is to report every order that is deleted and not filled, unless the order is the result of an entry error.

VII. RECOMMENDATIONS ON MERITS OF ALLEGATIONS AND OTHER FACTORS TO BE CONSIDERED

A. Recommendations on Merits of Allegations

Based on the factual information the Committee gathered during its investigation, and its understanding of the applicable law, the Committee does not believe that it is in the best interest of the Company to pursue claims for breach of fiduciary duty against the present and former directors named in the Demand Letter. The investigation shows that the Board at all times acted diligently and in good faith to fulfill its duties to the Company and the Company's shareholders.

The Letter alleges that the 2012 ISO was the result of a failure by the Company "to implement systems to detect and prevent the diversion of controlled substances into the illegal market" in accordance with the CSA and the 2008 MOA. (Demand Letter at 1, 10.) Further, the Letter alleges that the Directors and Officers of the Company "breached their duties of loyalty

[45] Since the 2012 ISO, the chains are more willing to collaborate with the Company on anti-diversion issues and the Company now receives more detailed information for individual chain stores.

and care when they knowingly and/or recklessly failed to establish" such a system of internal controls. (*Id.* at 10.)

As discussed, (*see supra* Part II), Ohio law provides that directors can be liable for damages only if they acted or failed to act with deliberate intent to cause injury to the corporation or with reckless disregard for the best interests of the corporation. *See* Ohio Rev. Code § 1701.59(E). Directors satisfy their obligation to remain informed of the corporation's activities if a reasonable information and reporting system exists within the company. *See Caremark*, 698 A.2d at 970-71. Where a reporting system exists, directors can be liable for breach of their oversight duty only if they ignore red flags that come to their attention warning of compliance problems. *See Stanley*, 2012 WL 5269147, at *6.

First, as this report makes clear, the Company implemented an extensive and robust system of internal controls to detect and prevent the diversion of controlled substances following the 2008 MOA, at a cost of approximately $25 million. The Board purposed for the Company to have a premier anti-diversion system. The Company brought in new management with extensive leadership, regulatory, and pharmaceutical experience, including Craig Morford, Gilberto Quintero, and Michael Moné, and hired experienced investigators and pharmacists to review potential new customers and monitor existing customers. The Company implemented an electronic monitoring system and set threshold ordering limits for customers based on statistical analyses of ordering data, and continued to improve the system and the underlying data. The Company developed a logistical regression model to compare existing customers to customers that had been terminated for posing unreasonable risks of diversion and hired a University Professor to validate the model. A centralized database was created to store and track data on customers and orders, thereby facilitating the monitoring process. Extensive policies and procedures were implemented for the anti-diversion group, salespeople, and personnel in the distribution centers. The Company administered anti-diversion training to thousands of employees. The Board was fully informed of the implementation of the anti-diversion measures, and received regular and detailed progress reports along the way.

Second, there were no red flags that the new anti-diversion controls were inadequate. The reaction of the Board, senior management, and QRA personnel to the 2012 ISO was one of surprise. The Company benchmarked the system with its competitors to the extent that it could, and hired outside consultants to test the system. By all accounts, management and QRA personnel were of the impression that the anti-diversion system was meeting or exceeding the Company's obligations to detect and report suspicious orders. Further, the Company received little, if any feedback from the DEA about the new system. The DEA reviewed the new anti-diversion system in early 2009 and inspected five distribution centers as part of the 2008 MOA. Although there were some initial concerns with one of the facilities, the Company rectified the issues and the DEA did not bring any formal proceedings. Moreover, the DEA conducted numerous routine cyclical inspections of the Company's distribution centers from 2008 through the end of 2011, and did not issue any negative findings regarding the anti-diversion measures. In fact, the DEA made positive comments during some of the inspections, indicating that the inspectors conducting those inspections were impressed, or at least satisfied with the compliance measures that were in place at the distribution centers. Senior management informed the Board that the inspections had been "successful" and that there were no negative findings regarding the SOM system from 2008 through 2011. In addition, management informed the Board that the

electronic monitoring system flagged thousands of orders and led the Company to terminate and report many customers, and reduce the volume being distributed to many other customers. The Board was also informed that enhancements to the system in 2011 increased the accuracy of the system and reduced the number of false positives by a significant amount.

Indeed, the Demand Letter fails to identify a single red flag following the 2008 MOA that would have indicated that the Company's diversion controls were inadequate. Instead, the Letter tries to draw a connection between the allegations at issue in the 2007/2008 Action and the allegations at issue in the 2012 ISO. In other words, the issues that existed before the 2008 MOA were the red flags that the Company's anti-diversion controls were inadequate leading up to the 2012 ISO. This reasoning fails for two key reasons. First, the Company undertook a complete overhaul of its anti-diversion measures following the 2008 MOA, and implemented an entirely new system. The facility at issue in the 2012 ISO, the Lakeland facility, was reinstated in 2008 and underwent a "Compliance Review" in 2009 as part of the 2008 MOA and a cyclical inspection in 2010, both without incident. Second, the events at issue in the 2012 ISO were different from those at issue in the 2007/2008 Action. The 2012 ISO involved the sale of oxycodone, not hydrocodone as in the 2007/2008 Action. Further, the pharmacies at issue in 2007/2008 Action were different from those at issue in the 2012 ISO. Finally, the 2012 ISO apparently stemmed from an unannounced shift by the DEA to a strict emphasis on volume, both for retail independent pharmacies, as well as for chain pharmacies.[46]

Moreover, the facts surrounding the pharmacies at issue in the 2012 ISO make clear that the system did not fail, but largely succeeded. Indeed, the electronic monitoring system alerted personnel to the increased ordering of each of the pharmacies at issue in the 2012 ISO, and at least one investigator alerted his superiors to certain indicators of diversion at the independent pharmacies. Ultimately, the Company stopped shipment to the two independent pharmacies at issue months before the Company received the 2012 ISO, and the Company's oxycodone sales to the two CVS stores had also drastically decreased by that time. Moné and Morse decided, after investigating the pharmacies and orders, not to terminate those customers for a period of time. The law does not hold directors liable for the judgment calls that each employee renders in executing the Company's policies and procedures. The directors were obligated to ensure that a reasonable information and reporting system existed. The Company implemented a robust system of internal controls to detect and report suspicious orders in accordance with the CSA and the 2008 MOA, and the directors were well-informed of those measures.

Because the directors did not fail to act in the face of any red flags that the Company's anti-diversion controls were inadequate, let alone fail to act with a deliberate intent to cause harm to the Company or with reckless disregard for the best interests of the Company, the Company cannot recover monetary damages from the directors. (*See* Ohio Rev. Code § 1701.59(E).)

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[46] The 2007/2008 Action involved retail independent pharmacies involved in "internet pharmacy" activity and such activity was, for the most part, readily apparent from viewing the pharmacies' websites, and from the fact that the prescribers were outside the area where the prescriptions were being filled.

B. Other Factors to Be Considered

The Committee also concludes that a review of other factors supports its determination that litigation of the sort requested in the Demand Letter is not in the best interests of the Company. The Committee employed its business judgment to consider all of the corporate interests that may weigh in favor of pursuing the proposed action.

The legal and factual deficiencies of the proposed action, as outlined above, would make it likely that the action would be dismissed before a decision on the merits, or that the action would conclude with a finding that the directors fulfilled their fiduciary duties to the Company. Further, the proposed action would be certain to consume tremendous Company resources. It is probable that pretrial discovery would last many months, and involve extensive document discovery, as well as discovery disputes and motion practice. Many, if not all of the twenty-two present and former Board members named in the Demand Letter would be deposed, as well as many officers and other personnel. It is also reasonable to assume that the parties would retain expert witnesses. In addition, the proposed action would distract management and employees from their daily responsibilities. Such distraction would result from the time and effort required to participate in the litigation, as well as the uncertainties created by criticisms of the Company's anti-diversion policies and procedures, and the execution of those policies and procedures by personnel.

Moreover, it is likely that the Company would be obligated to indemnify the directors for their costs in defending against the proposed action. All but two of the directors named in the Demand Letter signed an Indemnification Agreement, which provides that the Company may indemnify a director for costs and expenses he or she reasonably incurs in an action in which the director is made a party as a result of serving as a director of the Company, except where the director's conduct is found "to have been knowingly fraudulent, deliberately dishonest, or willful misconduct."[47] (*See* Indemnification Agreement §§ 1-2.) Because the directors acted in good faith at all times and diligently fulfilled their duties to the Company, the Committee concludes that the Company would likely be required to indemnify the directors for reasonable expenses they would incur in defending against an action of the sort requested in the Demand Letter. (*See id.*; *see also* Ohio Rev. Code § 1701.13.) The Committee finds that the expense of reimbursing the directors for litigation costs weighs against accepting the demand for claims with limited probability of success.

CONCLUSION

For the foregoing reasons, the Special Committee recommends that the Company not pursue the action requested by the Demand Letter.

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[47] Dave King and Clayton Jones, the most recent members of the Board, are entitled to indemnification under § 6.1 of the Restated Code of Regulations of Cardinal Health, Inc., which similarly provides for indemnification of costs and expenses that a director actually and reasonably incurs in an action where the director was a made a party as a result of his or her position as director.